

# Exhibit 10

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

IN RE JOHNSON & JOHNSON  
(LHG)  
TALCUM POWDER PRODUCTS  
MARKETING, SALES PRACTICES,  
AND PRODUCTS LIABILITY  
LITIGATION

MDL NO. 16-2738 (FLW)

*THIS DOCUMENT RELATES TO ALL CASES*

RULE 26 EXPERT REPORT OF  
SARAH E. KANE, MD

Date: November 15, 2018

  
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Sarah E. Kane, MD

I. BACKGROUND:

I am certified by the American Board of Pathology in Anatomic Pathology, Clinical Pathology and Cytopathology. I received my medical degree from The Ohio State University College of Medicine in Columbus, Ohio. I completed my residency in Anatomic and Clinical Pathology at Massachusetts General Hospital, a Harvard Medical School teaching hospital in Boston, Massachusetts. Following my residency, I completed a two-year gynecologic and cytology fellowship as the Robert E. Scully Fellow in Pathology at Massachusetts General Hospital, named after Dr. Robert Scully, who was a giant in the field of gynecologic pathology. This fellowship was focused on gynecologic pathology, perinatal pathology, and cytopathology. I studied the causes and mechanisms of disease as part of my training, and studied gynecologic cancer and disease in depth during my fellowship training. To this day, I routinely follow the gynecologic pathology literature as part of my regular practice.

I am currently a full partner in a private practice group, Commonwealth Pathology Partners PC. I have staff privileges at Massachusetts General Hospital, North Shore Medical Center (consisting of Salem Hospital in Salem, MA and Union Hospital in Lynn, MA) and Newton-Wellesley Hospital. I was hired by Commonwealth Pathology Partners PC to be the group's gynecologic pathology expert. Although all of the anatomic pathologists in our group practice general anatomic pathology, our group employs fellowship-trained pathologists in many subspecialty areas of pathology. This means that I see the majority of gynecologic surgical pathology specimens from my hospital sites, and if another pathologist needs an opinion on a gynecologic case, I will review it. I also presently serve as the autopsy director at North Shore Medical Center. I regularly attend and participate in numerous multidisciplinary conferences at Massachusetts General Hospital at the Cancer Center site in Danvers, MA.

Before entering private practice, I was a staff pathologist and Instructor of Pathology at Beth Israel Deaconess Medical Center (BIDMC), another Harvard Medical School teaching hospital. During my time at BIDMC, I performed specialty sign-out in gynecologic pathology, perinatal pathology and cytology. I was also served as the Associate Director of the Cytopathology Fellowship Program at BIDMC, served on numerous pathology department committees, and taught several courses at Harvard Medical School before I was recruited for my current position. My curriculum vitae is attached as Exhibit A. It further details these positions and the remainder of my work experience in this field. Exhibit B details the references cited in this report, as well as other materials and data I considered.

I have been asked to provide an expert report regarding my opinions on the question of general causality in the case of talcum powder product use and ovarian cancer. All of my opinions stated below are held to a reasonable degree of medical and scientific certainty. I reserve the right to modify or change my opinion based on further documents or information that may be provided to me in the future.

A pathologist is a physician who has completed medical school and a post-graduate residency in pathology (either clinical pathology, anatomic pathology, or both). Like me, many pathologists go on to complete fellowships following their education and residency.

Pathology is the study of disease; pathologists spend much of their time both in training and in daily practice studying the causes and presentations of disease. The years of medical training are of critical importance in daily practice; pathologists must make clinical assessments, based in part on medical and epidemiologic knowledge, about identification of causes, risk factors, clinical sequelae, morphologic, and genetic features of disease.

In order to produce accurate diagnoses, pathologists must be knowledgeable about the medical, scientific, and epidemiologic evidence base. A knowledge of advancements in technologies applied to tissue samples must be continuously maintained. This involves not only maintaining current knowledge of the pathology literature, but also of the literature in various other fields such as oncology and other fields relevant to our practice.

One of the tools used in the process of identifying talc particles in tissue is polarized light microscopy. Anatomic pathologists routinely use polarized light microscopy in clinical practice. As an example, one might use polarized light microscopy to find foreign material and explain an inflammatory reaction. The most common application in my practice is for identifying calcium oxalate crystals in breast biopsies done for radiologically identified calcifications. I estimate I use polarized light microscopy for this purpose about twice a month.

In anatomic pathology, the pathologist not only needs to be aware of the numerous possible diagnoses, but also of the causes of diseases one may encounter in any given organ system. Coming to a diagnosis requires knowledge of the medical, scientific, and epidemiologic literature. Pathologists must be proficient in the current literature that informs and supports their conclusions.

Ultimately, a pathologist's diagnosis must make biological sense and must be supported by the weight of the available medical and scientific information. Not only must a particular case match the morphological characteristics of the diagnosis being made, but it must fit the clinical presentation, the patient history, and it must be consistent with what is known about the disease, including what is known about disease causation. These are the same medical and scientific information resources that I rely on for my opinions in this report.

Thus, the work that I've done in this report is similar to what I do in my daily practice. My clinical practice requires ongoing familiarity with the same medical evidence that I have considered here.

Ovarian cancer has an incidence rate of 11.8 per 100,000, and thus is relatively rare (Torre 2018). At my current private practice, I am the primary pathologist on approximately 6,000 cases annually. This includes both surgical pathology and cytopathology cases. I would be diagnosing, ruling out, or looking for ovarian cancer or metastatic ovarian cancer (among other diseases), in approximately 2000 cases a year as a rough estimate. Of those, I estimate that I diagnose about 30 cases per year as ovarian tumors. Academic teaching hospitals generally tend to have a higher volume of ovarian tumor cases due to their large referral bases. While I was a staff pathologist at Beth Israel Deaconess Medical Center, the pathology department implemented a subspecialty sign-out schedule in 2010. In my last two years there,

I signed out predominantly gynecologic surgical pathology in addition to cytopathology (in prior years the department had a general surgical pathology schedule, which meant all types of cases went to each anatomic pathologist regardless of subspecialty fellowship training). During that time, I estimate I signed out about 500 ovarian tumor cases per year. Similarly, while I was a fellow at Massachusetts General Hospital from 2005-2007, I independently signed out gynecologic surgical pathology and estimate I signed out approximately 500 ovarian tumor cases per year. As a resident in anatomic pathology at Massachusetts General Hospital, I was exposed to hundreds of ovarian tumor cases both during my clinical case work and didactic sessions.

Of note, during my time at Massachusetts General Hospital, both Drs. Robert Scully and Debra Bell were still working in the Department of Pathology. Dr. Scully was a co-author on Dr. Cramer's first paper on talc and ovarian cancer in 1982, and Dr. Bell was a co-author on Drs. Harlow and Cramer's 1992 paper on talc and ovarian cancer. Dr. Bell's tenure as Cytopathology Director also overlapped with my time there. This meant that I spent significant time with Dr. Bell during my residency and fellowship. I was the primary author of a paper on ovarian serous borderline tumors in 2006, with Dr. Bell serving as a co-author. Dr. Scully, known as a giant in gynecologic pathology, was semi-retired by the time I started my pathology residency in 2001. However, he was at the hospital nearly every day and all of the gynecologic pathologists would still show him cases on a consult basis. Dr. Robert Young, the director of my fellowship program, was a Scully protege and continued his consulting practice. It is because of my training at Massachusetts General Hospital and my interactions with both Drs. Scully and Bell that I first became aware of their work on talc and ovarian cancer. Since then, I have maintained a professional interest in and have continued to monitor developments in the science regarding talcum powder exposure and ovarian cancer, and it has been the subject of professional discussions pre-dating this litigation.

My billing rate is \$500 per hour. I have previously testified in one matter, a deposition for the case of Julie Lagadimas, as Personal Rep. of the Estate of Dawn M. O'Toole v. R.J. Reynolds Tobacco Co., et al; Norfolk Super. Ct. Case No. 1582-CV-01474.

## II. GENERAL CAUSATION OPINIONS:

Based on assessing and weighing the totality of the evidence, and following the methodology set forth below, I hold the following opinions to a reasonable degree of scientific and medical certainty:

1. Talcum powder products and their constituent minerals can reach the ovaries through migration up the genital tract from the perineum to the fallopian tubes and ovaries. There is also evidence that these products can be transported through the lymphatic system (Cramer 2007). Another biologically plausible pathway is inhalation leading to lymphatic transport to the ovaries (Suzuki 1991, Marchiori 2010, Frank 2011).

2. Once reaching the ovaries, talcum powder products can cause chronic inflammation, can increase oxidative stress, and can reduce immune response. These are biologically plausible and likely mechanisms for ovarian cancer development and progression.

3. There are chemical similarities between asbestos and talc and there are striking pathological similarities between invasive serous ovarian cancer and mesothelioma.

4. There is evidence that talcum powder products manufactured by Johnson & Johnson (Johnson's Baby Powder and Shower to Shower) have contained and continue to contain asbestos, talc containing asbestiform fibers (fibrous talc), and heavy metals such as cobalt, nickel, and chromium. Other than cobalt, which has been identified as a "possible" carcinogen by the International Agency for Research on Cancer (IARC), all of these constituents have been identified as known carcinogens by IARC (IARC 1987, IARC 2012).

5. For purposes of my opinions, I have reviewed and relied upon Dr. Crowley's report regarding the fragrance chemical constituents in Johnson & Johnson talcum powder products (Crowley Report), as well as testing reports and analysis which include, Dr. Blount (Blount Report), Dr. Longo and Dr. Mark Rigler (Longo et al. Report), as well as the corporate testimonies of John Hopkins and Julie Pier. The presence of these constituents as part of talcum powder products provides additional evidence of biological plausibility for causation regarding talc and ovarian cancer.

My opinions and conclusions are supported by epidemiologic studies showing an increased risk of ovarian cancer in women who used talcum powder products for perineal dusting, animal and in vitro studies, cellular biology studies, and pathological evidence which provides a highly biologically plausible mechanism for talc's carcinogenicity. Based on the totality of evidence, it is my opinion to a reasonable degree of scientific and medical certainty, that perineal exposure to talcum powder products can cause epithelial ovarian cancer.

### III. METHODOLOGY FOR ASSESSING CAUSATION AND PRINCIPLES OF CAUSAL INFERENCE:

For this report, I followed the same methodology that I use in my clinical practice and research, a method that is generally accepted in the medical community. I used the same standards for evaluating and interpreting medical and scientific evidence, and I followed generally accepted standards in science and medicine for assessing causation, including consideration of the Bradford Hill viewpoints.

My causal assessment in this case is based on my background, training, education and experience as a physician and pathologist in interpreting, comparing, and weighing the totality of the available biologic, pathologic and epidemiologic evidence. I considered this evidence in the context of the Bradford Hill causation assessment viewpoints to reach an opinion regarding whether talcum powder products<sup>1</sup> can cause epithelial ovarian cancer.

Bradford Hill's discussion of a causal relationship includes strength of association, consistency, coherence, specificity, temporality, biological plausibility, dose-response, experimental evidence, and analogy as different "viewpoints" of a causal relationship between

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<sup>1</sup> In my report, the term "talc" is used to refer to talcum powder products.

an exposure and a disease. Consideration of Bradford Hill's approach to causation, which I discuss in more detail below, supports general causation of talcum powder product exposure and ovarian cancer. The Bradford Hill causation viewpoints are not a checklist of requirements, and it does not call for a mechanical application of his 9 considerations for assessing a causal relationship; rather, it is properly understood as providing a framework for an assessment of the totality of the evidence leading to a judgment about causation. As Bradford Hill himself put it, "What I do not believe...is that we can usefully lay down some hard-and-fast rule of evidence that must be obeyed....None of my nine viewpoints can bring indisputable evidence for or against the cause-and-effect hypothesis and none can be required as the *sine qua non*." I agree with that statement.

My methodology began with a systematic review of the medical literature to ascertain the relevant body of scientific evidence that I would consider. This included consideration of a large number of peer-reviewed publications reporting the results of human epidemiological studies investigating the association between talc exposure and ovarian cancer. I also considered and weighed other lines of evidence pertaining to explaining relevant, plausible, and likely mechanisms for how talcum powder product exposure causes ovarian cancer. This included carcinogenicity studies and data regarding talc and its constituents. Counsel for plaintiffs also provided me with medical literature to review, most of which overlapped with materials that I found independently through my own medical literature searches.

Relevance is not simply a yes/no proposition; it is a variable that ranges from not relevant to directly relevant, and there is a range between these extremes. Only a careful review of the evidence leads to an assessment of the degree of relevance. Much of science involves extrapolation and generalization from one study to the general population. The assessment of relevance is based on the extent that the study results are pertinent to the issue under consideration.

Human data is generally more relevant than animal data when assessing causation in humans. However, animal studies on exposure and disease are performed to advance our understanding of the human response to the same dose-adjusted exposure, and thus animal data is often relevant and important in that it can provide important information that forms part of the total evidence assessment. For example, if an exposure to talc in a rat causes inflammation, that could be relevant to assessing the effect in humans.

All observational studies have limitations, requiring careful interpretation. Reliability determinations focus on the degree of confidence in a study's internal validity. Reliability, like relevance, is not a yes/no proposition. For human epidemiologic observational studies, reliability assessments entail consideration of alternative explanations, including the role of chance and the likelihood that the results are affected by bias or confounding. Factors to be considered include: (1) Do we have reliable and appropriate measures of exposure; (2) do we have reliable assessments of disease; (3) do we have comparable groups for comparison; (4) have the investigators adjusted for potential confounding; (5) are the study results likely the result of a systematic bias; and, (6) does the study have enough exposures and sufficient power to detect an association if it exists?



I also consider the type of study design and whether it is suited to the question being researched. There is a general hierarchy of evidence, which I also consider, but study type and its position in the hierarchy will only have value if the study is otherwise relevant and reliable. For example, a randomized clinical trial may be the “gold standard,” but one must still look at whether the study does in fact provide a relevant and reliable result for the issue of interest (here, whether talcum powder products are capable of causing ovarian cancer).

In weighing the evidence other important considerations include: How does the study define, ascertain, and measure talc exposure? What type of study was it? Other considerations include: Has the study been or can it be replicated? Is the study result consistent with other studies? Has the study been published and has it been peer reviewed? Has the study been conducted on a relevant population? How does the study adjust for potential confounders and how does the study minimize or account for bias? Is there a potential for misclassification of exposure or disease based on the circumstances under which the data was gathered or analyzed? What is the potential that study results could be due to chance, bias, or confounding? Is there a statistical analysis, with a reported error rate? Were the results statistically significant, and, if not, are the results still important when considered with all other evidence from the perspective of overall consistency? What is the size of the study population? Is the study large enough to detect an association if it exists? Do the results make biologic sense? This is a list of examples of considerations for weighing the evidence, and is not intended to be comprehensive.

In weighing the evidence, I also consider the reported “P values” and confidence intervals (the result of statistical calculations), along with the reported relative risks and odds ratios, and other details about each study as explained above and below. The concept of “statistical significance” is often misunderstood. In assessing any statistical evidence pertaining to medical issues, medical and scientific researchers note whether certain findings are “statistically significant.” However, findings that are not “statistically significant” are often statistically and clinically important and should be considered and weighed along with other available evidence in making causal assessments. The concept of statistical significance using arbitrary cutoffs has no relationship to the strength or direction of an estimated association, and may have very little relationship with the actual validity of a study’s results. A “P value” of 0.05 or less is often considered statistically significant, whereas 0.06 is not.<sup>2</sup> I agree with the epidemiologists who consider this “cut-off” to be arbitrary, because, for example, the .01 difference between  $p = 0.05$  and  $p = 0.06$  is essentially the difference between a 5% vs. 6% probability that the observed association is due to the role of chance. Even where a confidence interval includes “1,” depending on the values of the lower and upper bounds of the confidence interval, the most likely interpretation of the study results may be that there is an association between an exposure and the increased risk of a disease.

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<sup>2</sup> In epidemiologic studies, epidemiologists or statisticians calculate a P-value and/or 95% confidence interval (“CI”) for each risk estimate. Essentially, the P-value and the CI assess the likelihood that the observed association is due to the play of chance. A 95% CI means that if the same experiment is repeated many times, 95% of the time, the true value of the risk estimate will fall between the upper and lower bound of the CI. The narrower the CI, the more precise and reliable the risk estimate is considered to be.



Bradford Hill stated that “[n]o formal tests of significance can answer those questions [of causation]. Such tests can, and should, remind us of the effects of the play of chance... Beyond that, they contribute nothing...” Therefore, in weighing the evidence, I note the P-value and/or the confidence interval reported with a study’s results, and consider this to be an important piece of information for interpreting study results. I do not think it is appropriate to disregard results just because they do not meet an arbitrary statistical threshold, a view also held by the American Statistical Association (Wasserstein 2016).

All observational studies have limitations, and the potential for “bias” and confounding. The presence of some bias is not generally a basis for scientists to disregard a study. Instead, when interpreting a study, biases must be considered and assessed for the likelihood that they may obscure, diminish, or magnify a study result, so the direction and magnitude of any bias must also be considered where possible. Some biases will have the effect of obscuring or understating an association between exposure and disease. Typically, study investigators will include as part of their published paper reporting the study results, the important strengths and limitations (including their assessment of the role of bias, chance and confounding) in the study.

In weighing the evidence, I also consider the likelihood that the study may understate or fail to detect an association that did exist (a Type II error, often due to lack of “power”); or the converse, that a study result may overstate an association or find an association that is not real (Type I error). In interpreting studies that do not report an association with an increased risk of ovarian cancer, one issue is whether the results provide reliable evidence of the absence of an association. The only way for data to provide statistical reassurance about the absence of an association is, in the absence of any important systematic error in the data, for the upper bound of a reasonable confidence interval (such as a 95% confidence interval) to be close to the null value.

When a study finds an association between exposure and disease, causation is one explanation, but it is not the only explanation. Other explanations must be considered and assessed. When an observational study results in a reported association between exposure and disease (i.e., relative risk or odds ratio greater than 1.0), and if alternative explanations (i.e., the role of bias, confounding and chance) are considered and determined to be unlikely explanations, then causation remains a likely explanation, subject to consideration of the Hill viewpoints. In order to reach an opinion that an association is causal between talc exposure and ovarian cancer, I considered whether there are other potential explanations that better explain the relationship and which are consistent with the totality of the scientific evidence. This assessment is informed by considering how a specific study fits into the overall totality of the evidence.

My opinions on causation are informed by a review of the strengths and limitations of the epidemiology evidence along with a review of other lines of evidence, including animal data and evidence on biological plausibility, likely mechanism(s) and dose/response. Thus, as part of my methodology, I have considered whether there is an alternative explanation to causation, based on an assessment of the totality of evidence. For example, I have considered whether the findings of the human epidemiologic studies are best explained by chance,

confounding or bias, when viewed separately, and most importantly, when viewed as a whole, and in light of the several lines of experimental evidence discussed in this report.

Based on my review of the totality of evidence, which I have weighed based on the considerations described above, I conclude with a high degree of medical and scientific certainty that exposure to talcum powder products can cause ovarian cancer. Causation is the best explanation for assimilating, assessing and weighing the totality of evidence. In reaching this opinion, I found it compelling that the epidemiologic studies that captured talc exposure consistently found an association between exposure to talc applied in the perineal area and epithelial ovarian cancer. The studies also provide persuasive evidence of a dose response effect, one of the viewpoints of causality discussed by Bradford Hill. There also is persuasive evidence of plausible and likely causal mechanisms for how talc exposure leads to ovarian cancer.

The other explanations for an association (other than causation) are bias, chance and confounding, and “reverse causation.”<sup>3</sup> While it may not possible when looking at a single study to determine whether a recall bias, or a selection bias, or a potential confounder is materially affecting the results, I find it helpful to consider how each study fits into the whole. Here, multiple studies have been conducted in different populations, by different investigators, using different methods, and using different study types, and yet there is general consistency in the results. The vast majority of studies and meta-analyses find an association with an increased risk of ovarian cancer. Under these circumstances, viewing the evidence as a whole, the likelihood that the consistent finding of an association can be explained by bias, or chance or confounding is highly unlikely, especially in light of the results of the other lines of evidence.

Finally, as part of my methodology of considering alternative explanations for the evidence, I made an effort to understand the opinions of both the plaintiff and defense experts as concerning the issue of talc and causation of ovarian cancer. In that regard I have reviewed some plaintiff and defense expert testimony and reports, which are identified on my reference list. I also cited to the extensive medical literature I considered in connection with my work on this report.

#### IV. MECHANISM OF TALC’S CARCINOGENICITY

There is a plausible and likely biologic mechanism whereby talc causes inflammation which can lead to epithelial ovarian cancer. Chronic inflammation has been causally linked to a number of cancers. The evidence of the relationship between inflammation and cancer is based on many studies, including studies supporting the

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<sup>3</sup> In epidemiology, reverse causation is when the exposure-disease process is reversed; In other words, the exposure causes the risk factor. Here, the question is whether exposure to talcum powder products causes ovarian cancer or whether ovarian cancer causes increased usage of talcum powder products? I am not aware of any evidence to support a conclusion that reverse causation is a plausible explanation for the association between exposure to talcum powder products and ovarian cancer. The principal presenting symptom is abdominal bloating, which does not appear to lead to more talc use.

conclusion that inflammation plays a role in increasing the risk of epithelial ovarian carcinoma. As stated by the National Cancer Institute, “Over time, chronic inflammation can cause DNA damage and lead to cancer. For example, people with chronic inflammatory bowel diseases...have an increased risk of colon cancer.” The time interval between inflammatory response and presentation of cancer can be many years. Animal studies, particularly, may show granulomatous or other inflammatory reactions while not necessarily demonstrating neoplastic changes due to the time interval required for cancer to develop.

Studies have shown that pelvic inflammatory disease and endometriosis (known to cause an inflammatory reaction) increase the risk of ovarian cancer (Risch 1995, Brinton 1997, Ness 2000, Brinton 2004, Kobayashi 2007, Lin 2011, Zhou 2017). Genofre et al. (2007) showed that talc can induce inflammation. Ness (1999) reported that inflammation of ovarian epithelium is a risk factor for ovarian cancer.

Inflammation has been implicated in carcinogenesis in several ways. Inflammation increases cytokines (Ness 1999). Shukla (2009) showed that nonfibrous talc can induce an inflammatory response that alters expression of genes in cancer pathways such as COX-2, ATF3, IL-6, and IL-8 in mesothelial cells. Further, inflammation increases oxidative stress (Ness 1999); Buz’Zard (2007) revealed that talc can induce oxidative stress and create reactive oxygen species (ROS), which in turn can induce ovarian neoplastic transformation in human ovarian cells. See also Saed (2017).

## V. INFLAMMATION

Inflammation can produce toxic oxidants such as ROS that can be a source of mutagenesis to DNA. This damage to DNA by ROS is now accepted as a major cause of cancer, and has been demonstrated in ovarian cancer (Senthil 2004, Saed 2010, Saed 2017) as well as in breast and hepatocellular carcinoma (Waris 2006, Saed 2017). Talc exposure has been shown to cause a statistically significant increase in ROS in ovarian polymorphonuclear neutrophils (PMNs), resulting in a decrease in cell viability and neoplastic transformation of ovarian cells. The authors concluded that “talc increased proliferation, induced neoplastic transformation and increased ROS generation time-dependently in the ovarian cells.” (Buz’Zard 2007)

Thus, it is accepted that inflammation causes oxidative stress. Oxidative stress leads to the formation of ROS and reactive nitrogen species (RNS). Oxidative stress is an important factor in the initiation and development of several cancers, including ovarian cancer (Senthil 2004, Saed 2010, Saed 2018). The production of oxidants and free radicals affects cellular mechanisms that control cell proliferation and apoptosis, which in turn play a role in the initiation and development of several cancers (Saed 2018). ROS and RNS can induce genetic mutations and DNA damage, thus causing oncogenic phenotypes. Additionally, oxidative stress affects transcription factors that modulate the expression of genes important to the development and metastasis of cancer cells (Saed 2018). Oxidative stress is also known to activate certain signaling pathways, which are critical for the initiation and maintenance of the oncogenic phenotype (Waris 2006). In fact, the major source of cellular ROS, the NAD(P)H

oxidase family of enzymes, has been linked to the survival and growth of tumor cells in pancreatic and lung cancers (Reuter 2010, Rojas 2016). Pro-oxidant enzymes such as myeloperoxidase (MPO), inducible nitric oxide synthase (iNOS), and NAD(P)H oxidase have been associated with initiation, progression, survival, and increased risk in cancers such as breast, ovarian, lung, prostate, bladder, colorectal, and melanoma (Lengyel 2010, Fletcher 2017, Saed 2017, Saed 2018). Angiogenesis is critical for the survival of solid tumors and is also regulated by ROS (Reuter 2010, Saed 2017). Thus, it is clear that alteration of oxidative balance can provide an environment for cancer cell survival (Saed 2018).

Gene point mutations resulting in single nucleotide polymorphisms (SNPs), or a variation in a single base pair in DNA, have been associated with oxidative DNA repair genes and redox genes with cancer susceptibility (Klaunig 2010). There is evidence that genetic polymorphisms in genes with anti-tumor activity are associated with cell cycle genes and play a role in ovarian cancer etiology (Goode 2009, Notaridou 2011). There are associations of specific SNPs in oxidant and anti-oxidant enzymes with increased risk and survival of ovarian cancer (Belotte 2015, Fletcher 2017).

Higher levels of oxidants have been described in epithelial ovarian cancer (Malone 2006, Saed 2010, Jiang 2011). Fletcher et al. published an abstract in the March 2018 Reproductive Sciences that showed talc can generate a pro-oxidant state in both normal ovarian epithelial and ovarian cancer cells. In this study, there was a marked increase in mRNA levels of the pro-oxidant enzymes iNOS and MPO in talc treated ovarian cancer cell lines and normal ovarian epithelial cells, as compared to controls within 24 hours. There was also a marked decrease in the mRNA levels of the anti-oxidant enzymes catalase (CAT), glutathione peroxidase (GPX), and superoxide dismutase 3 (SOD3), but a marked increase in glutathione reductase (GSR) and no change in glutathione S-transferase (GST) in the talc treated ovarian cancer cell line and in normal ovarian epithelial cells compared to controls within 24 hours (Fletcher 2018). In addition to tumorigenic cells generating high levels of ROS that activate signaling pathways which promote proliferation, it is known that tumorigenic cells maintain a high level of antioxidant activity to prevent buildup of ROS to levels that could induce tumor cell death (Schieber 2014, Saed 2017).

ROS and RNS are normally neutralized by enzymes such as SOD, CAT, GST, glutathione (GSH), thioredoxin coupled with thioredoxin reductase, glutaredoxin, glutathione peroxidase (GPX), and GSR (Lei 2016). Glutathione S-transferase is involved in detoxification of carcinogens by catalyzing their conjugation to GSH (Lei 2016). The GS-X-MRP1 efflux pump, which removes toxins from cells, is known to be stimulated by the GSH/GSSG complex and this process has been investigated as a mechanism for the development of tumor chemoresistance (Ishikawa 1993, Circu 2012).

Further, data demonstrates that talc exposure caused a statistically significant increase in ROS in ovarian polymorphonuclear neutrophils (PMNs), which resulted in a decrease in cell viability and neoplastic transformation of ovarian cells (Buz'Zard 2007).

Additionally, inflammation induces increased cellular proliferation, giving rise to potential DNA replication errors. This is one of the ways increased lifetime ovulations increase the risk of epithelial ovarian carcinomas. Studies have shown that ovulation results in an inflammatory response to disruption of the ovarian epithelium with the release of inflammatory mediators that initiate cellular transformation and growth (Richards 2002). Endometriosis causes an inflammatory reaction (including macrophage activation, cytokine release, and expression of growth factors) and is a risk factor for clear cell (Figure 4) and endometrioid (Figure 5) ovarian carcinomas (Risch 1995, Brinton 1997, Ness 2000, Brinton 2004, Kobayashi 2007, Edwards 2015). Studies have also shown that pelvic inflammatory disease (PID) is an ovarian cancer risk factor (Risch 1995, Brinton 1997, Ness 2000, Brinton 2004, Kobayashi 2007, Lin 2011, Zhou 2017). Several prospective studies suggest that elevated serum levels of inflammatory markers such as CRP, TNF- $\alpha$  and IL-6 are predictive of development of ovarian cancer (McSorley 2007, Lundin 2009, Clendenen 2011, Toriola 2011, Poole 2013, Trabert 2014, Gupta 2016).

There also are some studies showing a protective effect of anti-inflammatory drugs on the risk of developing carcinoma, although some studies have failed to show a protective effect (Wu 2009). An analysis of many randomized controlled studies did show a reduced risk of developing carcinoma with aspirin use (Rothwell 2012). A 2014 article specifically evaluating ovarian carcinoma analyzed pooled data from 12 population-based case-control studies and showed a reduction of ovarian cancer risk with frequent aspirin and high-dose non-steroidal anti-inflammatory (NSAID) use (Trabert 2014). This further supports the role of inflammation in carcinogenesis, as this effect cannot be explained by other etiologies (Baandrup 2013, Trabert 2014).

Talc is not an inert substance. It has been shown to cause inflammation. Studies have shown increases in markers of inflammation following talc exposure (Allaire 1989, Genofre 2007, Arellano-Orden 2013). Talc is used therapeutically for patients with recurrent pneumothorax and pleural effusions based upon its ability to induce inflammation and adhesions. Injecting talc into the pleural space causes an inflammatory and granulomatous reaction, causing fibrosis and scarring which prevents further pneumothorax development (Antonangelo 2006, Najmunnisa 2007). This is mediated through the release of cytokines and chemokines (Nasreen 1998, van den Heuvel 1998), and the production of basic fibroblast growth factor (bFGF) (Antony 2004). It is worth noting that asbestos fibers are also known to initiate an inflammatory and scarring process within the pleura and peritoneum, which can eventually lead to neoplastic transformation of the mesothelium. The time interval between the initial inflammatory response for asbestos and talc and the development of cancer can be many years. Remote exposure will not necessarily mean there will be evidence of current inflammation or foreign body reaction when tissues are examined.

There also is evidence that talc induces macrophage TNF- $\alpha$  expression (Cheng 2000). Macrophages that express TNF- $\alpha$  promote ovarian tumorigenesis (Hagemann 2006). TNF- $\alpha$  is involved in chronic inflammation and induces mutations in vitro (Yan 2006). TNF- $\alpha$  induced chromosomal mutations occur mostly in cells with p53 aberrations (Yan 2006). Of note, high grade serous carcinomas typically have inactivating mutations in p53. Both talc and TNF- $\alpha$  induce macrophage expression of IL-8 (Nasreen 1998, van den Heuvel 1998), which attracts



neutrophils that then release ROS. This in turn causes a feedback loop between ROS generation and increased TNF- $\alpha$  expression, causing increased DNA damage (Xie 2000). This is an important line of biological experimental evidence supporting my causation opinion. The strongest association of talc and ovarian cancer is with invasive serous carcinomas, which commonly have p53 mutations, and TNF- $\alpha$  induced chromosomal mutations occur mostly in cells with p53 aberrations. Talc has been shown to induce macrophage TNF- $\alpha$  expression, which has been shown to promote ovarian tumorigenesis.

## VI. ROLE OF IMMUNE SYSTEM IN CARCINOGENESIS

Studies have evaluated the protective role of the immune system in carcinogenesis, and in particular anti-MUC1 antibodies (Cramer 2005). MUC1 is a high molecular weight transmembrane protein expressed in many normal organs in a highly-glycosylated form. In cancer, including ovarian carcinoma, MUC1 is expressed at high levels in a poorly-glycosylated form. Anti-MUC1 antibodies are produced when high levels of the poorly-glycosylated form of MUC1 present to the immune system. Anti-MUC1 antibodies have been found in some cancers (Ho 1993, Dong 1997, Feng 2002) and have been associated with improved prognoses (Kotera 1994). Chronic processes including endometriosis, ovulation and talc exposure affect expression of MUC1 (Cramer 2005, Vlad 2006, Terry 2007). Decreased anti-MUC1 antibody production caused by these processes plausibly leads to immune-tolerance of an early ovarian carcinoma. Cramer et al. published a paper in 2005 that showed factors which increase the levels of anti-MUC1 antibodies lower the risk of ovarian carcinoma (Cramer 2005). Factors that decrease anti-MUC1 antibodies, such as incessant ovulation, have been associated with an increased risk of ovarian carcinoma (Terry 2007). Prospective data from the Nurses' Health Study (NHS) showed that tubal ligation increases anti-MUC1 antibodies, potentially by the procedure triggering the production of anti-MUC1, thus indicating another way tubal ligation exerts its protective effect. The study also showed that increased numbers of ovulatory cycles decrease anti-MUC1 antibodies, providing an explanation for the increased risk of ovarian cancer with increased lifetime ovulations (Pinheiro 2010). These studies provide evidence that MUC1 antibodies serve a role in the mechanism of and immune response in ovarian carcinogenesis. Because talc use is associated with a decrease in MUC1 antibody expression, the above is relevant to assessing the risk of talc use and ovarian cancer and provides further evidence supporting causation.

## VII. COSMETIC TALC

Cosmetic talc has been used for decades, applied directly or indirectly to the genital region because of its high absorbency and softness (Langseth 2008).

Talc is a magnesium silicate hydroxide, characterized by water molecules in between silicate sheets. Asbestos is also a silicate mineral, but is somewhat morphologically distinct from talc and belongs to different silicate mineral groups. However, the chemical similarity of asbestos and talc led some researchers to postulate that both talc and asbestos could be causes of ovarian cancer (Graham 1967, Henderson 1971, Longo 1979). Early research into the possible link between talc and ovarian cancer was also instigated due to the fact that high

grade serous carcinoma, a type of invasive serous epithelial ovarian cancer (Figure 1), shown to be most commonly associated with perineal talc use, has striking morphologic similarities to mesothelioma (Figure 2), the tumor most associated with asbestos (Graham 1967). High grade ovarian serous carcinoma and mesothelioma express similar immunohistochemical markers, most notably cytokeratin pattern, WT-1 and calretinin. In fact, a great deal of surgical pathology literature deals with the nuances in differentiating peritoneal mesothelioma from high grade serous carcinoma. In the last few years, additional immunohistochemical panels have been developed that help distinguish between these two tumors (Laury 2010, Ordonez 2013), including PAX8, which is also expressed in fallopian tube epithelium. The morphologic and immunohistochemical similarities between asbestos and talc malignancies constitute another line of evidence supporting my opinion that talc exposure in the genital area causes ovarian cancer. Later in this report, I address the evidence that asbestos exposure can cause ovarian cancer.

#### VIII. TALC MIGRATION, TRANSLOCATION, INHALATION, AND LYMPHATIC TRANSPORT

In order for cosmetic talc applied to the perineum to reach the ovary or fallopian tube and exert a neoplastic effect, it needs to travel up through the vagina and uterus. It is known that substances can travel proximally through the female genital tract to the fallopian tubes and ovaries (Egli 1961, Venter 1979). Several studies have demonstrated the presence of talc in ovarian tissue (Henderson 1971, Henderson 1979, Mostafa 1985, Heller 1996) and even in the pelvic lymph nodes of a woman with ovarian cancer and long-term genital exposure to cosmetic talc (Cramer 2007). This is evidence that talc can be transported through the lymphatic system. Thus, another biologically plausible pathway is inhalation leading to lymphatic transport to the ovaries (Suzuki 1991, Marchiori 2010, Frank 2011).

There is evidence that serous ovarian cancers are actually of fallopian tube origin (Piek 2003, Kindelberger 2007, Kurman 2010, Erickson 2013). When considering whether talcum powder can cause ovarian cancer, this consideration is not critical. Talcum powder particulates reach both the fallopian tubes and ovarian surfaces by migrating proximally.

#### IX. TALC IN TISSUE

As mentioned above, several studies have demonstrated the presence of talc in ovarian tissue (Henderson 1971, Henderson 1979, Mostafa 1985, Heller 1996) and one study found talc in the pelvic lymph nodes of a woman with ovarian cancer and long-term genital exposure to cosmetic talc (Cramer 2007). In Cramer et al.'s 2007 paper, the methods used by Dr. John Godleski to identify talc particles in tissue are outlined (Cramer 2007).

Tissue was first analyzed using polarized light microscopy to identify birefringent particles within the tissue plane. Polarized light microscopy is used in routine practice in anatomic pathology. One of the most common uses in surgical pathology is for the identification of calcium oxalate calcifications in breast tissue. In some lesions of the breast,



ranging from benign to malignant, calcifications occur that can be a marker for disease and are discovered on breast mammography. After mammography reveals calcifications and the radiologist determines them to be suspicious for disease, the area with calcifications is biopsied. The biopsy sample is then X-rayed to confirm the presence of the calcifications, and then submitted to the pathology laboratory for histologic analysis and diagnosis. The pathologist correlates the calcifications seen under the microscope with those in the specimen X-ray to be sure the calcifications the radiologist identified are visualized in the tissue sample. Calcium oxalate is a certain type of calcification that is not easily seen on light microscopy. If there appears to be a discrepancy between the tissue under light microscopy and the specimen X-ray (lack of calcifications under light microscopy), the pathologist will use polarized light microscopy to help identify calcium oxalate crystals, which are birefringent. Similarly, Dr. Godleski used polarized light microscopy to identify birefringent material that could be further analyzed using SEM and EDX.

SEM was more commonly used in surgical pathology before immunohistochemical studies were routinely used and before the common availability of molecular testing. However, SEM is still routinely used as an important diagnostic tool in areas of pathology in which immunohistochemical studies and molecular testing are less helpful, such as medical renal pathology, neuromuscular disorders and rare tumors. SEM uses electrons for imaging, analogous to light microscopy using light. SEM allows for much greater magnification (>100,000X) than light microscopy.

EDX is a qualitative and quantitative chemical analysis used in conjunction with SEM. It detects X-rays emitted from the sample during electron scanning to determine the elemental composition of the particle being examined. EDX is widely used in many biomedical areas, as it provides precise information on the chemical composition of subcellular structures that can be correlated with their SEM images (Wyroba 2015).

In Cramer et al 2007, the authors analyzed four pelvic lymph nodes from a 68 year old woman with ovarian papillary serous carcinoma and a small component of clear cell carcinoma. She had been a daily talc user for 30 years, having applied it to underwear and sanitary napkins. The lymph nodes showed birefringent particles via polarized light microscopy and were then analyzed by SEM and EDX. This showed magnesium and silicate signatures consistent with talc (Cramer 2007). Of note, there are similar studies performed with asbestos fibers in tissue sections (Roggli 1983, 1986).

Additionally, studies have shown Raman microscopy can be used to identify talc spectra in routinely processed, but unstained, histologic pathology specimens. Raman microscopy uses laser light to elicit the chemical and microstructural characterization of materials (Campion 2018).

Although the presence of talc particles found in ovarian cancer tissue does not prove that the talc played a causal role, when considered with the other lines of evidence supporting causation discussed in this report, the presence of talc in ovarian cancer tissue is certainly consistent with causation and provides additional evidence in support of a causal relationship between talcum powder products and ovarian cancer.

## X. EPIDEMIOLOGICAL DATA REGARDING TALC USE AND OVARIAN CANCER:

As detailed below, there is consistent evidence from multiple observational studies, pooled analyses, and meta-analyses that exposure to talcum powder products is associated with an increased risk of ovarian cancer. When combined and considered with the biological evidence described above, this consistent epidemiologic data from multiple studies provides strong evidence that the association is, in fact causal.

Although occasional studies have not found talc powder applied to the perineum or contraceptive diaphragms<sup>4</sup> to be a significant risk for developing ovarian cancer, as detailed below, most have found an association, and the cumulative evidence from these studies, when considered with the other lines of evidence discussed above, provides strong and compelling evidence of a causal association.

## XI. CASE-CONTROL STUDIES

Henderson first observed talc particles embedded in both ovarian tumors and normal ovaries (Henderson 1971). The first epidemiologic study on genital talc use and the risk of ovarian cancer was a case-control study by Cramer et al. (Cramer 1982). In this study, 215 women with epithelial ovarian cancer and 215 age-matched controls were questioned about talc use on the perineum and/or on sanitary napkins; 42.8% of ovarian cancer patients reported regular use of talc (prior to developing ovarian cancer) compared to 28.4% of controls, with an odds ratio (OR) of 1.92 (95% confidence level (CI) 1.27-2.89). The greatest risk in this study occurred in women who had used talc powder both directly on their perineum and on sanitary napkins compared to women who had no history of talc powder use; the odds ratio was 3.28 (CI 1.68-6.42). Of note, Cramer et al. did not exclude women from the control group who had a history of hysterectomy or other “pelvic surgeries” if the patient had intact ovaries by self-report. This could potentially lead to an underestimate of the risk of talc and ovarian cancer, as the controls may have had other confounding factors. They did control for confounding factors such as age, parity, religion, education, age of menarche, oral contraceptive use, hormone replacement therapy and smoking history.

While case control studies may have limitations with selection bias, Cramer et al. state “Our sample of cases represents more than 50% of ovarian cancer cases diagnosed

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<sup>4</sup> It is likely that studies based on talc with diaphragm use are generally limited to use by women for birth control purposes. This will not capture use before or after the women’s use of diaphragms for contraceptive purposes, a potential of multiple years that will not be captured in the study. Even for the years when women are using diaphragms, it is likely they are not using diaphragms for birth control on a daily basis. Therefore, diaphragm studies are likely to be biased toward the null; i.e., likely to understate talc exposure, and for that reason are likely to fail to detect an association that actually exists or understate the magnitude of risk.

in Boston residents in the study period. Therefore, it is difficult to conceive of a plausible bias in the selection of cases that would yield this excess use of talc.” (Cramer 1982)

In addition to the Cramer 1982 study, numerous other case-control studies addressing talc use and ovarian cancer have shown statistically significant odds ratios greater than 1, indicating talc use is associated with an increased ovarian cancer risk (Harlow 1989, Booth 1989, Harlow 1992, Chang 1997, Cook 1997, Green 1997, Godard 1998, Cramer 1999, Gertig 2000, Ness 2000, Mills 2004, Merritt 2008, Wu 2009, Moorman 2009, Rosenblatt 2011, Kurta 2012, Houghton 2014, Wu 2015, Schildkraut 2016, Cramer 2016).

In a 1983 letter to the editor in JAMA in response to the 1982 Cramer study, Hartge and Hoover state that they found an association between genital talc use and ovarian cancer with a RR of 2.5, but the sample size was small (7 cases to 3 controls), resulting in a wide confidence interval (0.7-10.0). They did not find an association between ovarian cancer and body talc use or talc use on diaphragms, but again the sample sizes were small (Hartge 1983). Similarly, a study published by Tzonou et al. in 1983 showed no association between perineal talc use and ovarian cancer (RR 1.05; CI 0.28 to 3.98) but the frequency of reporting talc use was low in the study population, thus the wide CI (Tzonou 1983).

Whittemore et al. published a case-control study in 1988 that showed a RR of perineal talc use and ovarian cancer of 1.40, with a p value of 0.06. They did not see an increased risk of ovarian cancer in women who used talc on sanitary napkins or diaphragms. They did see an increased risk of ovarian cancer in women who used perineal talc for 1 to 9 years compared to those who used it for a shorter period (RR 1.60, p=0.05, CI 1.00-2.7) but did not see an increase with perineal talc users greater than 10 years (RR 1.11, p=0.61, CI 0.74-1.65). A strength of this study is that participants were not only asked about their history of talc use, but also about their history of cigarette smoking, coffee and alcohol consumption, thus addressing recall bias. A possible limitation of this study is the fact that the control group was a combined group of two separate control groups: one hospital based from the hospitals where the cases were admitted, and one community based. It was not described for what conditions the hospital controls were admitted (Whittemore 1988).

In 1989 Booth et al. published a study that showed an increased risk of ovarian cancer in daily talc users (RR 1.3, CI 0.8-1.9) and weekly talc users (RR 2.0, CI 1.3-3.4) as opposed to monthly (RR 0.7, CI 0.3-1.8) and rare (RR 0.9, CI 0.3-2.4) users. There were limitations of this study, however; participants were limited to women younger than 65 who had been diagnosed within the two years prior to interview. The data was adjusted for age in 5 year stratas and socio-economic status, but socio-economic status was based upon husband’s career if married and participant’s career if never married. Strengths, however, included queries of hormone replacement therapy, type of contraceptive use, and duration of oral contraceptive use; this helps to address recall bias. Additionally, hospital-based controls admitted for gynecologic disease and breast cancer,

among other diseases, were excluded and hospital admission diagnoses were listed (Booth 1989).

Harlow's 1992 study included 235 women with epithelial ovarian cancer and compared them to 239 control women matched for age, race and residence. After adjusting for age, parity, weight, education, marital status, religion, use of sanitary napkins and douching, it was found that talc use increased the ovarian cancer risk by 50% (OR=1.5, CI 1.0-2.1). Harlow's 1992 study also involved a dose-response effect; duration and frequency of perineal talc use was calculated into lifetime talc applications. Lifetime application ORs, when compared to control women with no perineal talc exposure, were 1.3 for <1000 (CI 0.7-2.7), 1.5 for 1000-10,000 (CI 0.9-2.4) and 1.8 for >10,000 (CI 1.0-3.0) (Harlow 1992). A dose response effect is a consideration in assessing causation. Harlow, Terry (2013) and Wu (2015) studies provide clear evidence of a dose effect. Particular strengths of the Harlow study are the number of potential confounding factors adjusted for and the detailed history on type of use and duration of use. Women with body exposure (non-genital) were considered non-exposed. Additionally, in the Harlow study, women were also asked about dietary and smoking histories, which helps to address potential recall bias.

Rosenblatt et al. published a study in 1992 that showed an increased risk of ovarian cancer with talc use (OR 1.7, but a small sample size with CI 0.7-3.9) (Rosenblatt 1992). In the Rosenblatt study, participants were also asked about oral contraceptive use and hormone replacement therapy, which helps to address potential recall bias. Another study published in 1992 by Chen et al. evaluated the association between talc use and ovarian cancer in a Beijing population. They found a RR of 3.9 in women with a history of use greater than 3 months, but the sample size was small with a 95% CI of 0.9-10.63. They also included dusting powder to the lower abdomen as well as perineum (Chen 1992), which would likely understate the magnitude of the association.

A 1997 study published in the journal *Cancer* by Chang et al. analyzed 450 patients with either ovarian borderline tumors or invasive ovarian carcinomas and showed an increased risk of tumor in women with either direct perineal application of talc or talc use on sanitary napkins (OR=1.42 after adjusting for age, parity, tubal ligation, hysterectomy, duration of oral contraceptive use, length of breastfeeding after pregnancy, and family history of ovarian cancer CI 1.08-1.86). For invasive ovarian carcinomas, the adjusted OR was 1.51 (CI 1.13-2.01). For borderline tumors, the adjusted OR was 1.24 (CI 0.76-2.02) (Chang 1997). The authors found that a borderline-significant association between duration of talc exposure and risk (OR 1.09, 95% CI 0.98-1.21, per 10 years of exposure). No significant association was found between frequency of exposure and risk. In comparing invasive and borderline carcinomas, risk remained elevated for both carcinoma types. The study did not assess for non-genital talc use. A particular strength of this study is that the same questions regarding talc use were asked about cornstarch use; they found no significant risk of ovarian cancer with cornstarch use (OR 0.31, CI 0.06-1.66), although only 1% of the populations reported using cornstarch (Chang 1997). Still, this helps to reconcile potential confounding risk factors of ovarian cancer in people more likely to use perineal powder. The interviews with participants also included taking

histories on oral contraceptive use and hormone replacement therapy, which helps to address recall bias.

Cook et al. also published a study in 1997 that evaluated 313 women with epithelial ovarian tumors (both invasive and borderline) and 422 controls. Only white women were included. They found that there was an increased risk of ovarian cancer with direct perineal powder dusting of 60% (OR=1.6, CI 1.1-2.3) and 90% (OR=1.9, CI 1.1-3.1) for genital deodorant sprays sprayed directly onto the perineum. Lifetime number of talc applications provided evidence of dose-response: a statistically significant increased risk (OR=1.7, CI 1.0-2.9 for less than or equal to 500 applications, OR=2.6, CI 0.9-7.6 for greater than 500 applications). A strength of this study is that participants were asked about smoking and contraceptive use, which helps to address recall bias. A limitation of this data is that all types of powder were included, such as cornstarch, "baby powder," "deodorant powder," and "scented body/bath powder." However, the authors state, "No specific type of powder used for perineal dusting, diaphragm storage, or on sanitary napkins was strongly related to ovarian cancer risk, although there was a suggestion of an elevated risk associated with any use of talcum powder and bath/body powders (RR = 1.6, 95 percent CI 0.9-2.8, and RR = 1.5, 95 percent CI 0.9-2.4, respectively)." (Cook 1997)

In 1997, an Australian study performed by The Survey of Women's Health Study Group enrolled 824 women with epithelial ovarian tumors, both invasive and borderline, and 855 controls. They found that the risk of ovarian cancer was highest among women who were talc users and had not undergone surgical sterilization (RR=1.3, CI 1.1-1.7) after adjusting for age, parity, duration of oral contraceptive use, BMI, smoking, education and family history of ovarian cancer. The risk was lowest in women who had not applied talc to their perineum and had either a tubal ligation or hysterectomy (RR=0.6, CI 0.50-0.84) (Green 1997). Because tubal ligation limits transport of talc fibers to the ovary, this study, with a finding of a protective effect in women with tubal ligation, provides an important piece of additional evidence. Strengths of this study include high response rate (90% of cases and 73% of eligible controls) and the verification of past surgical procedures by contacting participants' surgeons. Additionally, participants were asked questions about other potential exposures such as smoking histories and pelvic inflammatory disease, which helps to address recall bias. Limitations include a lack of data on quantity of talc use.

In 1999, Wong et al. published a paper that did not show a consistent association with talc powder and ovarian cancer, evaluated by length of use as follows: talc use for 1-9 years (OR 0.9; 95% CI 0.6, 1.5), 10-19 years (OR 1.4; 95% CI 0.9, 2.2), or more than 20 years (OR 0.9; 95% CI 0.6, 1.2). This was after adjustment for age at diagnosis, parity, oral contraceptive use, smoking history, family history of epithelial ovarian cancer, age at menarche, menopausal status, income, education, geographic location, history of tubal ligation, and previous hysterectomy. However, this study would tend to understate the magnitude of an association with genital talc use because it included talc use on thighs as well as genitals. The study used hospital controls, which raises a question of whether the controls were comparable to the cases (Wong 1999).



As part of Cramer et al.'s 1999 study, 563 women with newly diagnosed epithelial ovarian cancer were compared to 523 controls, and showed that perineal talc users had a significantly increased odds ratio for epithelial ovarian cancer (OR=1.60, CI 1.18-2.15). The effect of talc use was even stronger for invasive serous carcinoma (OR=1.70, CI 1.22-2.39). This was after adjusting for age, parity, oral contraceptive use, body mass index and family history of breast or ovarian cancer. The higher risk for women with invasive serous carcinoma was replicated in other studies, and this is an important finding in these studies because of its specificity. In addressing potential recall bias, Cramer et al. state, "...recall bias seems more likely to affect exposures that have occurred over a short term than those that have occurred over a long term. Since average duration of talc use exceeded 20 years in both cases and controls in our current study, genital talc exposure may be less likely to be subject to recall bias... It also seems reasonable that selective recall would lead to cases reporting all types of talc exposure more frequently than controls, but our study found that cases did not report a significant excess of talc use in non-genital areas compared to controls. Finally, if recall accounted for the association, one would expect little variation in the odds ratios by histologic type of ovarian cancer.... Regarding potential bias from confounding, we found no evidence that genital talc exposure varied by key risk factors for ovarian cancer such as age, parity or [oral contraceptive] use and little variability of the association by these and other variables." (Cramer 1999)

Ness et al.'s 2000 study evaluated 767 women with ovarian epithelial borderline tumors and ovarian invasive cancer compared to 1367 controls. Consistent talc use, defined as at least once per month for six or more months, increased the ovarian cancer risk by 50% (OR=1.5, CI 1.1-2.0) when applied to the perineal area directly and increased the risk by 60% (OR=1.6, CI 1.1-2.3) when used on sanitary napkins. This is after adjusting for age, parity, tubal ligation, hysterectomy, duration of oral contraceptive use, breast feeding and family history of ovarian cancer (Ness 2000). One explanation of the increased risk of talc use on sanitary napkins is that sanitary napkins may keep a larger amount of talc closer to the vagina over the course of several hours, thus increasing the risk of entry to perineum, while talc directly applied to the perineum may more easily disperse, however, many studies have failed to show an increased risk in ovarian cancer in participants whose only exposure to talc was on sanitary napkins. The strengths of this study include addressing multiple confounding factors. No dose-response was found; weaknesses include that only duration information was available, and genital/rectal talc use durations reported were combined with duration of use on the feet. Additionally, women who used just once per month were categorized as a user. These weaknesses may cause an underestimation of risk, and may have accounted for the lack of dose-response found.

Mills et al. published a study in 2004 that evaluated the association between talc use and ovarian cancer among 256 cases of ovarian cancer as compared to 1122 controls. Women diagnosed with invasive epithelial ovarian cancer with a history of genital talc use had an increased risk of 51% (OR=1.51, CI 1.07-2.12). This increased risk increased to 77% (OR=1.77, CI 1.12-2.81) for women diagnosed with invasive serous carcinoma.

Dose-response effects were also found. Increasing frequency of use was associated with increasing risk; women who reported use 4–7 times per week had a 74% elevation in epithelial ovarian cancer risk ( $p$  for trend = 0.015). However, the risk decreased between the second and third categories of use (from “rarely to several times per month” and “1–3 times per week” at 1.34 (CI 0.87–2.08) to 1.16 (CI 0.74–1.81), respectively). Duration of use of talc was also associated with increased risk, although the risk peaked among those reporting 4–12 years of use and declined somewhat among those reporting longer duration of use ( $p$  for trend = 0.045). Cumulative use also demonstrated an uneven association with risk of epithelial ovarian cancer in that the point estimates peaked in the second and third quartiles of intensity but declined in the highest quartile of use. These findings were after adjusting for age, race/ethnicity, duration of oral contraceptive use and duration of breast feeding. Yet, there wasn’t adjustment for first relative history of breast or ovarian cancer, pregnancy history, parity, BMI, hysterectomy, tubal ligation or hormone replacement therapy; according to the authors, the Hosmer-Lemshow goodness-of-fit tests revealed that after terms for duration of oral contraceptive use and duration of breast-feeding were added to the models, fit was not improved by the addition of these variables, nor were the estimated odds ratios altered by the addition of several of these variables (Mills 2004). However, the fact that participants were queried about other possible exposures such as hormone replacement therapy helps to address potential recall bias.

In Wu et al.’s 2009 study, women were found to be at increased risk of ovarian cancer if they had a history of prior perineal talc use, with the risk increasing significantly in those with long term (20+ years) and frequent (at least daily) use with a relative risk of 2.08 (CI 1.34–3.23), i.e., a dose effect. The authors did find an increased risk in women who used talc on sanitary napkins (RR 1.61, CI 0.93–2.78), underwear (RR 1.71, CI 0.99–2.97) and diaphragms/cervical caps (RR 1.14, CI 0.46–2.87). There was a stronger association between talc use and serous ovarian cancer; the relative risk with any talc use was 1.70 (CI 1.27–2.28). Strengths of this study include the adjustment for multiple possible confounding factors (age, race/ethnicity, education, age of menarche, parity, oral contraceptive use, family history of ovarian or breast cancer, menopausal status and tubal ligation). Another strength was that participants were queried about NSAID and endometriosis histories, helping to address potential recall bias. The authors mention in their discussion that the participation response was “modest,” possibly leading to selection bias (Wu 2009).

Rosenblatt et al. published a study in 2011 that showed an overall increased risk of ovarian cancer in women who used talc after bathing (OR=1.27, CI 0.97–1.66) with a more pronounced risk in women diagnosed with mucinous borderline tumors (OR=1.78, CI 0.98–3.23) and serous borderline tumors (OR=1.47, CI 0.85–2.55) (serous borderline tumor illustrated in Figure 3). They did not see an increased risk by extent of use, defined as years in which powder was used, or as lifetime number of applications. There was no alteration in the risk of ovarian cancer associated with other types of powder exposure such as sanitary napkins or diaphragms. This study did not find an increased risk of invasive serous carcinoma (OR 1.01, CI 0.69–1.47). (Rosenblatt 2011) A strength of this



study is that participants were queried about other potential exposures (smoking, alcohol and endometriosis histories), which helps to address recall bias.

In 2012, Kurta et al. evaluated talc use and the risk of ovarian cancer, although their main focus of the study was the associated risk of ovarian cancer with fertility drug use. They found a OR of 1.40 (CI 1.16-1.69). Since talc was not the primary focus of this study, duration of use was not considered; participants were categorized as talc users if they had ever used talc versus never-users. Perineal talc use was only generally defined as dusting powder or deodorizing spray on the genital or rectal areas, sanitary napkins, underwear, or diaphragms or cervical caps (Kurta 2012). A strength of this study is that its main focus was on fertility drug use; participants were asked about exposures such as fertility treatments and hormone replacement therapy, which helps to address potential recall bias.

Wu et al. published a paper in 2015 that evaluated talc use and invasive ovarian cancer in white, Hispanic and African American women. They found that talc use was more common in African-American women (44.1%) than in non-Hispanic whites (30.4%) or Hispanics (28.9%) ( $p=0.001$ ). The results showed ORs of 1.41 for white women (CI 1.21-1.67), 1.77 for Hispanic women (CI 1.20-2.62) and 1.56 for African American women, although the CI for African American women was 0.80-3.04. Overall, the OR was 1.46 (CI 1.27-1.69). However, the response rate and sample size for this study was somewhat small, and participants with less than one year of use were categorized as never users (Wu 2015).

In 2016, Schildkraut et al. published a paper as part of the African American Cancer Epidemiology Study (AACES), a case-control study of epithelial ovarian cancer in African American women. According to the authors, due to the relatively small number of women who reported having only used genital powder (43 cases and 44 controls), the authors merged this exposure category with those who reported use of both non-genital and genital powder, creating an exposure category of “any” genital powder use, but separately evaluated the categories as “only” or “any” genital powder use. They reported an increased risk of ovarian cancer in “any” genital powder users (OR=1.44, CI 1.11-1.86) and noted a statistically significant dose response effect for both duration of use and lifetime applications. A strength of this study was adjustment for multiple confounding factors such as age, education, BMI, parity, tubal ligation, OCP use, first degree relative with breast or ovarian cancer, and interview year (taking into account litigation cases in the year 2014). Participants were also asked about hormone replacement therapy, another potential exposure, thus helping to address potential recall bias. A weakness of this study is that participants were considered “regular users” if they reported using cornstarch, baby or deodorizing powders at least one time per month for at least 6 months, and “never users” if they did not, leading to possible misclassification that would bias toward the null (Schildkraut 2016).

The totality of the results of the case-control studies support a causal link between talc and ovarian cancer. When observational studies find an increased risk of disease with a certain exposure, the possible reasons are chance, bias, confounding and causation.

There is a general consistency of these individual studies; the ORs have been of similar magnitude in studies spanning different decades, in different populations, with different study designs, by different investigators, over different continents and with adjustment for multiple confounders. Therefore, the possibility that the association between perineal talc use and ovarian cancer is due to chance is extremely unlikely.

Although retrospective case-control studies potentially have an element of recall bias and other potential biases, again, the consistency of results across these studies and populations makes recall and other bias an unlikely explanation. During the period that the majority of studies were conducted, public awareness of the link between talc and ovarian cancer was limited. There is also a much stronger and statistically significant association of perineal talc use and ovarian cancer in studies that compared all-body talc use to perineal use. The finding in some studies that serous carcinoma has a stronger association with perineal talc exposure than other histologic subtypes of ovarian cancer also argues against recall bias, as participants are very unlikely to have knowledge about the histologic subtyping of ovarian cancer. In addition, in studies where participants are asked to recall multiple exposures, not just talc exposure, this will minimize the risk of recall bias because it is unlikely that participants will differentially recall talc exposure but not other exposures, especially if they are blinded to the study hypothesis. Studies using trained interviewers, structured interview questionnaires, and blinding of both study participants and the interviewers to the study hypotheses will also limit the potential for recall bias.

Selection bias (which can arise based on differential participation rates or other differences between comparison groups) accounting for the results across studies is also unlikely. To see such consistent associations between perineal talc use and ovarian cancer, there would need to be strong associations between participation and perineal talc use, and strong differences amongst cases and controls due to selection bias only - this would be extremely unlikely to produce such large biases across studies. Most studies adjusted for confounders, with the majority adjusting for age, BMI, and parity among others. With chance, bias, and confounding being unlikely explanations for the association of perineal talc use and ovarian cancer across multiple studies, this leaves causation as the most likely explanation.

## XII. COHORT STUDIES

The talc literature includes several cohort studies reporting the relative risk for perineal talc use and risk of ovarian cancer, including the Nurses' Health Study, the Women's Health Initiative and the Sister Study (Gertig 2000, Gates 2008, Gates 2010 and Gonzalez 2016). There were several important limitations of these studies to adequately capture risk of ovarian cancer based on the methodology used by the researchers to assess talc exposure.

The Gertig study evaluated prospective cohort data from 78,630 women, and although there was a 12% overall increased risk of ovarian cancer in women with a history of daily genital talc use, this was not statistically significant. Yet, the investigators

reported a statistically significant increased risk of invasive serous carcinoma (RR=1.4, CI 1.02-1.91) after adjusting for age, parity, duration of oral contraceptive use, post-menopausal hormone use, tubal ligation, BMI and smoking (Gertig 2000). Additionally, the lack of statistical significance of overall ovarian cancer risk may be due to several important limitations with this study, including the fact that the question of talc use was only in one questionnaire in 1982 and did not include questions on duration of use. Thus, a person who used talc just a few times would be included with women who used talc daily over a long duration, and this will have the effect of understating the risk. In fact, in a follow-up 2008 report, Gates et al. noted that since talc exposure was only referred to once in questionnaires, it is possible that some participants were misclassified with respect to their talc use or that some women may have started talc use after 1982 and thus these women would not be included in the talc user group (Gates 2008). This would understate the risk and decrease the calculated statistical significance of talc-related ovarian cancer. An additional review of the Nurses' Health Study published by Gates et al. in 2010 studied 876 cases of ovarian cancer and talc use, although this was not the primary focus of the study. This study found an overall increased risk of ovarian cancer with talc use (RR=1.06), but found an increased risk for mucinous tumors (RR=1.50) (Gates 2010) (mucinous carcinoma illustrated in Figure 6). Again, the weaknesses in the study include the fact that talc use was only queried once in 1982, and the authors state themselves that the limited data on talc use may have influenced the observed association with ovarian cancer.

Cohort studies like the Nurses' Health Study, Women's Health Initiative Study and the Sister Study have some drawbacks when studying rarer diseases compared to case-control studies that have been described above. Cohort and case-control studies are both observational, and both have strengths and limitations. Cohort studies begin when all participants are free of the disease in question. After a follow-up period, those that have the disease being studied are compared by exposure risk being studied to those who did not develop the disease. Although this helps to ensure exposure predates disease, there may be a lack of data if the disease is rare or if there is a long latency period between exposure and disease presentation/diagnosis, as is the case of ovarian cancer and talc. In contrast, in case-control studies, patients already have the disease being studied and are compared to controls who do not have the disease with a focus on the rates of exposure to the agent of interest (here, talcum powder products) in the cases as compared to the controls. A possible limitation of case-control studies in the context of ovarian cancer and talc is the fact that exposure to talc is self-reported and subject to potential recall bias.

The case-control studies may unavoidably have recall bias, as talc use was self-reported by participants. In their 2018 meta-analysis discussed below, Penninkilampi et al. noted that in some studies, interviewers were not blinded to cases and controls and many studies did not describe whether their controls had a personal history of previous ovarian cancer. However, they also noted that in general, controls were well matched to cases by other possible confounding factors such as age, geographic, location and ethnicity (Penninkilampi 2018).

In the 2008 Gates paper, women with certain variants in glutathione S-transferase M1 (GSTM1) and/or glutathione S-transferase T1 (GSTT1) were shown to have a higher risk of talc-associated ovarian cancer. Glutathione S-transferases catalyze the conjugation of glutathione to numerous potentially genotoxic compounds. Individuals with homozygous deletions of GSTM or GSTT have reduced or no glutathione S-transferase activity and may be unable to eliminate electrophilic carcinogens as efficiently (Coughlin 2002). The 2008 Gates study included 1,175 cases and 1,202 controls from a case-control study and 210 cases and 600 controls from the prospective Nurses' Health Study. Participants were genotyped for the GSTM1 and GSTT1 gene deletions and three NAT2 polymorphisms. Regular talc use was associated with increased ovarian cancer risk in the combined study population (relative risk=1.36, CI 1.14-1.63; p-trend<0.001). In the pooled analysis, the association of talc and ovarian cancer was stronger among women with the GSTT1-null genotype (p-interaction=0.03), particularly in combination with the GSTM1-present genotype (p-interaction=0.03). There was no clear evidence of an interaction with GSTM1 alone or NAT2. Without talc exposure, these genes were not clearly associated with risk of ovarian cancer (Gates 2008). The specificity of the findings linking the genetic polymorphisms with ovarian cancer subtype most associated implicates yet another aspect of the Bradford Hill viewpoints.

As previously detailed, the Nurses' Health Study also showed that genital talc use was associated with lower levels of anti-MUC1 antibodies, which has been associated with an increased risk of ovarian cancer. As part of the Nurse's Health Study, Pinheiro et al. published a paper in 2010 that showed increasing anti-MUC1 antibody levels were associated with a nonsignificant trend for a lower risk of ovarian cancer with highly significant heterogeneity by age (p-heterogeneity=0.005). The authors concluded that anti-MUC1 antibodies evaluated several years prior to diagnosis may be associated with lower risk of subsequent ovarian cancer in women less than 64 years old at assessment (Pinheiro 2010). Cramer et al. 2005 study showed factors which increase the levels of anti-MUC1 antibodies lower the risk of ovarian carcinoma (Cramer 2005). These findings provide evidence that a plausible mechanism for talc-associated ovarian cancer is a down-regulated immune response to MUC1, and thus an immune tolerance of an emerging MUC1-expressing tumor.

The Women's Health Initiative Observational Study (WHI-OS) did not report a statistically significant increased risk of ovarian cancer with talc use (Houghton 2014). In that study, 61,576 women were enrolled and 429 developed ovarian cancer during follow-up. The study did find a 12% increased risk of ovarian cancer in perineal talc users (RR=1.12, CI 0.92-1.36), but it was not statistically significant. However, the risk of developing serous carcinoma was increased by 18% (RR=1.18, CI 0.89-1.56), and by 13% for invasive serous carcinoma (RR=1.13, CI 0.84-1.51). Additionally, 101 cases were categorized histologically as "other," including tumors that were self-reported, not validated and potentially may not have even been primary ovarian tumors. This would bias the risk estimate of talc use in ovarian cancer in this study toward the null by including cancers or other tumors potentially from other sites; in other words, non-specific cancer types may have been included that are not known to have an association with talc use. Another weakness of the study is that although the authors did evaluate the

effect of duration of use of genital talc on the risk of ovarian cancer, they did not evaluate frequency of use. Thus a woman who used talc for twenty years once a month would be treated the same as a woman who used it every day for twenty years. This will tend to understate or obscure the true risk of long term, frequent use. The study also was of an older age group (50-79) who were post-menopausal at time of enrollment, which adds selection bias.

Another study in which the effect of talc use on the risk of ovarian cancer is likely diluted or understated is the Sister Study, published by Gonzalez et al. in 2016. In this study, there was no reported association between perineal talc use and subsequent ovarian cancer. The study only enrolled women with a full or half-sister who had been diagnosed with breast cancer. BRCA1 and BRCA2 mutations are associated with a markedly increased risk of both breast and ovarian cancer, and in the Sister Study, women were not tested for this mutation. Most of the ovarian cancers associated with BRCA mutations are of the invasive serous subtype, the same subtype most strongly associated with talc use in prior studies. By not testing the women for the genetic mutation, the Sister Study analyzed a population of women with an increased risk of having a BRCA mutation (by having a first degree relative, or sister/half-sister, with breast cancer), a significant confounding factor that was not considered. Another limitation of this study is that the mean follow-up was 6.6 years, a very short period considering the generally long latency period of ovarian cancer. The Sister Study did find an increased risk in ovarian cancer in women who douched, providing evidence supporting the link between particulate route of access to the ovary/fallopian tube. The histologic subtype of the ovarian cancer was also not evaluated. Further, similar to the other cohort studies, the Gonzalez 2016 study failed to adequately capture both duration and frequency of talc exposure as participants were only asked if they used talc in the last 12 months.

### XIII. META-ANALYSES REGARDING TALC USE AND OVARIAN CANCER:

Meta-analyses are an important tool that combines study results from multiple studies to develop a single result that has greater power to detect a more precise estimate of risk. Several meta-analyses have been published on the association between talc use and ovarian cancer, all showing an increased risk (Harlow and Cramer 1992, Gross and Berg 1995, Cramer and Harlow 1999, Huncharek 2003, Langseth 2008, Berge 2018, Penninkilampi 2018).

In 1992 Harlow and Cramer published combined results from six case-control studies of the association between talc use and ovarian cancer that were performed between 1982 and 1989. The association was statistically significant (OR=1.3, CI 1.1-1.6) (Harlow 1992). In 1995, Gross and Berg published a meta-analysis that included the six case-control studies evaluated in the 1992 Harlow and Cramer paper, plus three additional studies. This produced a statistically significant increased risk (OR=1.27, CI 1.09-1.48) (Gross 1995). Of note, this study was supported in part by Johnson and Johnson, raising the issue of funding bias.



Cramer published another meta-analysis in 1999 that included the nine studies in Gross and Berg's 1995 paper plus five additional ones performed through 1999. The overall risk of ovarian cancer in talc users was found to be increased at 36% (OR=1.36, CI 1.24-1.49) (Cramer 1999).

Huncharek et al. performed a meta-analysis in 2003 that added five new studies and included all of the previous studies except the 1983 Hartge and 1996 Shushan studies. The OR in this study was 1.33 (CI 1.16-1.45). Interestingly, the authors concluded that even with this statistically significant OR, the data "do not support the existence of a causal relationship" between talc use and ovarian cancer (Huncharek 2003). In a subsequent paper published by Huncharek et al., support from Johnson and Johnson and Luzanec America was acknowledged (Huncharek 2007), raising the issue of funding bias.

Langseth et al. published a comprehensive meta-analysis in 2008 of the risk of ovarian cancer associated with talc use. The combined OR was 1.35 (CI 1.26-1.46), and specifically 1.4 for population-based studies (CI 1.29-1.52), the less potentially biased type of study. Langseth et al. also noted that the risk of serous ovarian tumors in particular with talc use may be greater (Langseth 2008).

In 2016, Cramer published a retrospective case-control study that incorporated data from three enrollment phases (1992-1997, 1998-2002 and 2003-2008) and combined data from the Nurses' Health Study (Gates 2008) and data from participants in the Ovarian Cancer Association Consortium (OCAC, Terry 2013). The study found a statistically significant increased risk of invasive serous, invasive endometrioid and serous borderline ovarian tumors in women who were genital talc users, with the highest risk (OR=2.33 (CI 1.32-4.12) and OR=2.57 (CI 1.51-4.36) for pre- and postmenopausal women, respectively) with the greatest lifetime exposure, as defined by "talc-years," or number of applications per year multiplied by years of use. A dose-response was most prevalent for invasive serous carcinoma. This study is important as evidence supporting an association between talc and ovarian cancer as the authors analyzed case-control data collected over 16 years in 2,041 epithelial ovarian cancer cases and 2,100 age- and residence-matched controls. As the authors state, they "addressed issues related to definition of the exposure, bias and confounding, effect modification, histologic heterogeneity, and dose-response. Talc used regularly in the genital area was associated with a 33% increase in ovarian cancer risk overall." (Cramer 2016)

Berge et al. published another meta-analysis in 2018 that found a summary RR of 1.22 (CI 1.13-1.30). They found that the association between talc and ovarian cancer was stronger in case-control studies (RR 1.26, CI 1.17-1.35) than cohort studies (RR 1.02, CI 0.85-1.20). The limitations of the cohort studies are discussed above; limitations of case-control studies are recall bias and selection bias. Addressing the latter, Berge et al. found a higher summary risk estimate in hospital-based case-control studies compared to community-based case-control studies, but this difference was not statistically significant. Recall bias can be present in case-control studies, however, Berge et al. found the greatest association between genital talc use and serous carcinoma (RR 1.24, CI 1.15-

1.34). This would argue against recall bias, as participants would likely not know the categorization of epithelial ovarian tumors, nor the fact that invasive serous carcinoma has been shown to have the strongest association in the majority of studies.

Penninkilampi et al. published a meta-analysis in 2018 that found any perineal talc use was associated with an increased risk of ovarian cancer (OR 1.31, CI 1.24-1.39). They found a dose-response effect with greater than 3600 lifetime applications (OR 1.42, CI 1.25-1.61) compared to less than 3600 lifetime applications (OR 1.32, CI 1.15-1.50). Similar to the Berge 2018 study, an association was found in the case-control studies (OR 1.35, CI 1.27-1.43) but not in the cohort studies (OR 1.06, CI 0.90-1.25). However, Penninkilampi et al. did find an association in cohort studies between talc use and invasive serous carcinoma (OR 1.25, CI 1.01-1.55). (Penninkilampi 2018)

#### XIV. POOLED STUDY REGARDING TALC USE AND OVARIAN CANCER:

The meta-analyses discussed above summarize previously published data and thus have increased statistical power for a more precise estimate of effect on talc in ovarian cancer risk (Cohn 2003). However, the strength of meta-analyses depends on the quality of the previously published data analysis. In comparison, a pooled study analyzes primary data from different studies/researchers. The Terry 2013 study is a retrospective pooled study from eight population-based case-control studies from OCAC. One advantage of pooled studies is the ability to include a large sample size; Terry et al. included 8,525 cases of ovarian, fallopian tube or perineal cancer and 9,859 controls. Some of the included OCAC studies had previously reported on powder use (Chang 1997, Cramer 1999, Merritt 2008, Moorman 2009, and Rosenblatt 2011), and according to Terry et al., three of these provided data for the pooled 2013 analysis that had not been included in the previous publications. The other three studies had not previously published their genital powder data (Goodman 2008, Lo-Ciganic 2012, Pike 2004). The pooled analysis showed an OR for genital talc use and epithelial ovarian cancer of 1.24 (95% CI 1.15-1.33) after adjustment for age, oral contraceptive use, tubal ligation, BMI and race/ethnicity (Terry 2013). This is consistent with the majority of meta-analyses and individual studies.

A strength of a pooled study versus a meta-analysis is that pooled studies have increased standardization. As an example, the Terry 2013 study excluded participants that data was not available on regarding tubal ligation, oral contraceptive duration, parity or height and weight. This adjusts for study-specific differences in confounding factors. A weakness of pooled studies is that they are limited by the methods of original data collection; for example, Terry et al. state "Limitations of our pooled analysis include differences in the wording of questions about genital powder use between studies and the retrospective nature of the exposure ascertainment." As Blettner (1999) stated, "Pooling decreases the variation caused by random error (increasing the sample size) but does not eliminate any bias (systemic errors)." In the 2013 Terry et al. study, classification between cases and controls differed between studies, as the women who were classified as genital powder users varied from "ever" use, "ever regular" use, to powder use for at least one year. However, Terry et al. conclude that if anything, this led to an underestimate of the true association for any given



study “[due to the fact that] exposure definitions are the same for cases and controls within each study, misclassification of genital powder exposure due to the question wording would be nondifferential....” (Terry 2013).

XV. ASBESTOS, TALCUM POWDER PRODUCTS, AND OVARIAN CANCER:

I have seen evidence that talcum powder products manufactured by Johnson & Johnson (J&J Baby Powder and Shower to Shower) contained and continue to contain asbestos, talc containing asbestiform fibers (e.g. talc occurring in a fibrous habit) heavy metals (such as cobalt, chromium, nickel) and fragrance chemicals (Longo et al. 2017 and 2018, Blount 1991, Blount Deposition 2018, Hopkins Deposition and Exhibit 2018, Pier Deposition and Exhibit 2018). Other than cobalt, which has been identified as a “possible” carcinogen, all of these constituents have been identified as known carcinogens by IARC (IARC 2012). It should be noted that National Institute for Occupational Safety and Health (NIOSH) has determined that “there is no safe level of asbestos exposure for any type of asbestos fiber” (NIOSH 1980). As part of my review and consideration of the evidence I have also reviewed Dr. Michael Crowley’s opinion that “fragrance chemicals in Johnson & Johnson talcum powder products contribute to the inflammatory properties, toxicity, and potential carcinogenicity of the products.” The presence of these constituents as part of the talcum powder product provides additional evidence of biological plausibility for talcum powder products to cause ovarian cancer.

Asbestos is a silicate mineral in polyfilamentous bundles. Other silicate minerals exist, such as talc, but asbestos is classified by its flexible fibers with small diameter and large length. The forms of asbestos are serpentine silicates (“sheet silicates”) such as chrysotile, and amphibole silicates (“chain silicates”) such as crocidolite, amosite, anthophyllite, actinolite, and tremolite (IARC Monograph). The carcinogenic properties of asbestos fibers depend on the length of the fiber (Stanton 1972) and its chemical composition, structure, and cell environment (Mossman 1998, Robledo 1999, IARC Monograph). Asbestos fiber surface reactivity with free radical generation has also been accepted as a mechanism of carcinogenesis (IARC Monograph). Asbestos-derived free radicals can lead to a variety of effects on cells including lipid peroxidation, DNA oxidation, TNF release, cell apoptosis, and increased uptake of asbestos fibers (Mossman 1983, Hobson 1990, Ghio 1998, Churg 1998, Gulumian 1999, Aust 1999, Upadhyay 2003, IARC Monograph). Asbestos fibers may directly cause the generation of ROS (IOM 2006) and indirectly cause ROS by inducing inflammation and macrophage activation (IARC Monograph).

It has long been generally accepted that asbestos exposure causes mesothelioma and lung cancer (Dement 1994, deKlerk 1996, Berry 2000). Approximately 125 million people around the world have been exposed to asbestos in work environments, and at least 90,000 people die each year from asbestos-related lung cancer, mesothelioma, or asbestosis (Burki 2009). The relationship between asbestos exposure and ovarian cancer had been less studied; however, in 2009, the IARC Monograph Working Group concluded that there is sufficient evidence to show that asbestos exposure can cause ovarian cancer (Straif 2009, IARC Monograph).

In the late 1960's, a suggested link between talc and ovarian cancer was made for the following reasons: first, talc powders were shown to contain asbestos (Cralley 1968); second, intraperitoneally placed asbestos in animals induced a proliferation of the ovarian mesothelial lining from one layer to multiple layers (Graham 1967). Of note, it was tremolite asbestos that was used by Graham, the same type of amphibole asbestos that is found in asbestos-contaminated talc. It is important to note that similar to talc being found on the ovarian surfaces of perineal talc users, asbestos fibers have been found in women whose household contacts worked with asbestos and in Norwegian paper and pulp workers (Heller 1996, Langseth 2007).

In 1972, Newhouse et al. published a study of the mortality of female asbestos workers and found at least 4 deaths due to ovarian cancer compared to an expected number of 0.6. During histological review of some of the pathology samples from these workers, there was evidence that another two deaths that had been registered as due to carcinomatosis were likely caused by ovarian cancer (Newhouse 1972).

Ten years later in 1982, Wignall et al. published a study that followed 535 women who were assembly workers that had direct crocidolite exposure during the manufacturing of military gas masks. The authors found 2 deaths due to ovarian cancer in women that were employed at the facility for less than 1 year, with a standardized mortality rate (SMR) of 1.77. Two ovarian cancer deaths occurred in women with a 1 year history of employment at the facility (SMR=2.11) and one ovarian cancer death in a woman with a 3 year history of employment (SMR=1.05). The authors noted that the expected number of deaths is low, making stable estimates of SMR difficult. However, the authors conclude that the "excess of deaths from carcinoma of the ovary was unexpected at the start of the study but appears to be related directly to exposure to asbestos" (Wignall 1982).

Also published in 1982 was a study by Acheson et al. that evaluated two groups of women exposed to asbestos who assembled gas masks in two separate facilities: 570 women at Blackburn (civilian respirators that contained chrysotile) and 757 women at Leyland (military respirators containing crocidolite). The study found a SMR in the crocidolite group for ovarian cancer of 2.75 (CI 1.42-4.81) and a SMR of 1.48 (CI 0.48-3.44) for the chrysotile group. The authors noted that the risk of ovarian cancer increased over time for up to 40 years post exposure (Acheson 1982).

A 1994 study by Rosler et al. examined mortality from ovarian cancer in a cohort of 616 women in Germany who had been occupationally exposed to asbestos. Although about 95% of asbestos used in Germany was chrysotile, the authors noted that they could not exclude a mixture containing crocidolite. Two deaths from ovarian cancer were observed, compared to an expected 1.8 (SMR 1.09, CI 0.13-3.95). (Rosler 1994).

In 1999, Germani et al. published a study of ovarian cancer mortality in 631 women workers in Italy who had been compensated for asbestosis. They found a total of nine ovarian cancer deaths (SMR 4.77, CI 2.18-9.04) which included four deaths in a subset of asbestos-textile workers (SMR 5.26, CI 1.43-13.47) and five deaths in the subset of asbestos cement workers (SMR 5.40, CI 1.75-12.61). (Germani 1999).

Also in 1999, Vasama-Neovonen et al. published a case-control study of ovarian cancer and occupational exposure in Finland. The Standardized Incidence Ratio (SIR) was 1.30 (CI 0.9-1.80) between ovarian cancer and “medium/high levels of asbestos,” and the SIR was 1.1 (CI 0.8-1.3) for “low levels of asbestos.” The SIR is obtained by dividing the observed number of cases of cancer by the expected number of cases in the general population. The type of asbestos fiber was not noted (Vasama-Neovonen 1999).

Again in 1999, Langseth et al. published a study of 4247 workers employed for at least one year between 1920 and 1993 in the Norwegian pulp and paper industry. 85% of them were paper or administration workers. The follow-up period for cancer was from 1953-1993. An excess risk of ovarian cancer was found (SIR = 1.50, CI 1.07-2.09). The SIR was highest among those younger than 55 years, and mostly among those working in paper departments. The type of asbestos fiber was not specified (Langseth 1999). Langseth et al. published a follow-up case-control study in 2004 that examined the association between asbestos exposure and ovarian cancer in this same cohort of female pulp and paper workers in Norway that had been found to have excess morbidity from ovarian cancer. In the case-control study, the odds ratio for occupational exposure to asbestos based on 46 cases of ovarian cancer was 2.02 (CI 0.72-5.66), although this was not statistically significant (Langseth 2004).

In 2000, Berry et al. published a study that evaluated the mortality of a cohort of over 5000 London asbestos factory workers, both men and women, who were followed for over 30 years since first asbestos exposure. The study classified exposure by degree (low, moderate and severe) and duration (2 years or less or more than 2 years). They assessed mortality by comparing the number of cohort deaths with the number of expected deaths in England and Wales based on sex, age and period. The study found that there was a significant increase of ovarian cancer in women with severe exposure for more than 2 years (SMR of 5.35) and an overall SMR for all exposure lengths of 2.53 (CI 1.16-4.8) (Berry 2000).

In 2005, Pira et al. published a cohort study of 1077 women with at least a one month history of employment between 1946 and 1984 at an asbestos-textile factory in Italy. A variety of asbestos types were used in this facility, including crocidolite. They followed up with the cohort in 1996. There were five deaths due to ovarian cancer with an overall SMR of 2.61 (CI 0.85-6.09), but there was a SMR of 5.73 for women with longer employment histories at the facility (greater than or equal to 10 years of employment). Among women with greater than or equal to 35 years since first employment exposure, the SMR was 5.37 (Pira 2005).

Also in 2005, Wilcsynska et al. published a study of 1470 Polish asbestos cement factory workers with a follow-up period from 1945 to 1999 and a SMR of ovarian cancer among workers of 3.76 (CI 1.38-8.18). The type of asbestos fiber was not specified (Wilcsynska 2005).

McDonald et al. published a study in 2006 that followed 567 people, mostly women, who had assembled gas masks in the Nottingham factory between 1940 and 1944 and showed

a SMR for ovarian cancer of 1.2 (CI 0.6-2.2). Gas masks assembled at this facility had filter pads that contained 20% crocidolite. As an aside, this study found that the first deaths due to mesothelioma happened a little more than 20 years after exposure, which is consistent with most other studies (McDonald 2006) and highlights the lengthy time interval between exposure and presentation of disease in asbestos-related mesothelioma.

In 2008 Reid et al. published a study of 2552 women and girls who lived in a Western Australia mining town between 1943 and 1992 where crocidolite asbestos was mined. They were not directly involved in mining but there was extensive environmental contamination of the town. They found a SMR for ovarian cancer of 1.52 (Reid 2008).

Reid et al. published a study in 2009 that followed the same cohort of 2552 women and girls in Western Australia with environmental exposure to crocidolite asbestos and added 416 women to the study that had worked in the Wittenoom crocidolite asbestos mines and mills. For the latter group, there wasn't an increased rate of ovarian cancer (SIR of 0.49, CI 0.01-2.74), but the authors noted that the "female Australian Blue Asbestos workers at Wittenoom mostly worked in the company offices, shop, and hotel. Their occupational exposure was unlikely to have been as high as that reported for women in the earlier cohorts, which may explain why no excess risk for ovarian cancer was observed" (Reid 2009).

Pukkala et al. published a study in 2009 on the incidence of ovarian cancer in women employed in various occupations in Denmark, Finland, Iceland, Norway and Sweden. One of the groups examined were plumbers, who are known to have occupational exposure to asbestos. Four ovarian cancers were found in this group of plumbers, with a Standardized Incidence Rate (SIR) of 3.33 (CI 0.91-8.52). Fiber type was not specified (Pukkala 2009).

Magnani et al. and Bertolotti et al. published studies in 2008 that followed the same cohort of former asbestos-cement workers who were employed at a facility in Casale Montferrato, Italy. A mix of crocidolite and chrysotile asbestos was used at this factory. They observed nine ovarian cancer deaths versus 4 expected (SMR of 2.27). In women who had 30 or more years of exposure, the SMR was 2.97 (Magnani 2008, Bertolotti 2008). Ferrante et al. published a study in 2007 that examined cancer mortality in the household contacts of men who worked at this facility; among women with exposure due to household contacts, there were 11 ovarian cancer deaths versus an expected 7.7, or SMR of 1.42 (CI 0.71-2.54). (Ferrante 2007).

I am aware of two meta-analyses, both published in 2011, that evaluated a link between asbestos and ovarian cancer. The first was published in 2011 by Reid et al. and analyzed fourteen cohort and two case-control studies of women with exposure to asbestos in their work environment. The majority of the cohort cases they evaluated are detailed above. The authors added a 2002 paper by Szeszenia-Dabrowska et al. that studied Polish women diagnosed with asbestosis and a 2004 paper by Mamo et al. that studied Turin asbestos textile factory workers (Szeszenia-Dabrowska 2002, Mamo 2004). The two case-control studies they evaluated were a 1992 study of Johns Hopkins patients by Rosenblatt et al. and a 2004 study

of Norwegian pulp and paper workers by Langseth et al., the same group of workers previously described above. Reid et al. concluded that although women “thought to have ovarian cancer” (not all cases of ovarian cancer were histologically reviewed and confirmed) had an increased rate if exposed to asbestos, the overall numbers were still small and further study was warranted as one misclassification could skew the data (Reid 2011).

The authors of the second 2011 meta-analysis, Camargo et al., included 18 studies. They did not include the 1992 Rosenblatt et al. study or the 2004 Langseth et al. study but added six others: a 1986 study of cement workers in the U.K. by Gardner et al., a 1989 study of friction material workers in the U.K. by Newhouse et al., a 2007 study of textile workers in the U.S. by Hein et al., a 2009 study of textile workers in the U.S. by Loomis et al., and two other 2009 studies by Harding et al. and Clin et al. The authors of this second meta-analysis came to a stronger conclusion that the findings were consistent with an association between asbestos exposure and an increased risk of ovarian cancer (Camargo 2011).

Considering the consistency of these studies, the Bradford Hill viewpoints (strength of association, consistency, biological plausibility, etc.) and the well-known carcinogenic properties of asbestos, it is my opinion to a reasonable degree of scientific certainty that asbestos exposure can cause ovarian cancer. Even disregarding the evidence that cosmetic talc is contaminated with asbestos, it is my opinion that talc is causally associated with ovarian cancer. However, to the extent that talcum powder products contain even small amounts of asbestos, the evidence of causation is even more compelling.

## XVI. BRADFORD HILL ANALYSIS:

In 1965, Sir Austin Bradford Hill proposed nine viewpoints of a causal relationship: strength of association, consistency, specificity, temporality, biologic gradient, plausibility, coherence, experiment and analogy (Hill 1965). It is important to remember, however, as discussed at the beginning of this report, that Hill himself noted that none of these viewpoints of association – including the existence of a statistically significant relationship – is either necessary or sufficient to show causation. There are no “hard-and-fast rules”. Rather, the totality of the evidence must be weighed and considered. With that important command in mind, let us examine the evidence.

### 1. Strength of association:

Strength of association is often measured by the magnitude of the relative risk (CDC). All meta-analyses and pooled analyses have found a statistically significant increased risk of ovarian cancer in perineal talc users, with relative risks falling between 1 and 2. This is consistent with a causal relationship. Strength of association is higher for asbestos. There are a number of examples of causal relationships where the relative risk is less than 2.0 (e.g., second hand smoke and lung cancer, oral contraceptive use and breast cancer, radon exposure and lung cancer). It also is worth noting that small or moderate effects on the benefit side can have important clinical significance. For example, aspirin has been deemed “causal” of cardiovascular event reduction, based on multiple studies that reported a benefit between 20-30% reduction in cardiovascular events. The strength of this association, especially combined



with the consistency, weigh in favor of a cause-and-effect relationship between talc and ovarian cancer.

## 2. Consistency:

The statistically significant increased risk of ovarian cancer with talc use has been consistent in size across multiple studies, different populations, different investigators, multiple countries and over time. Hill stressed the importance of repetitive findings; no single study can prove or disprove causation due to possible inherent internal validity issues. The consistency of the increased risk of ovarian cancer (and in particular invasive serous carcinoma) with talc use found in numerous studies, in different countries, and after adjustments for confounding factors cannot be disregarded. There also is consistent evidence of an association between asbestos and ovarian cancer. This was a very important factor in my analysis.

## 3. Specificity:

Hill suggested that associations are more likely to be causal when they are specific, in other words, a particular substance causes a single disease. However, in the half-century experience has shown that this aspect of causation is not particularly important in the context of cancer. Few examples of specificity are found when it comes to cancer. Smoking is generally accepted to be a cause of lung cancer, yet smoking is also associated with COPD, heart disease, stroke, and asthma, amongst other diseases. In multiple studies, talc has been shown to be associated with epithelial ovarian cancer, with invasive serous ovarian cancer showing the strongest association. Asbestos is generally accepted to cause mesothelioma, lung cancer, and ovarian cancer. Asbestos is also generally accepted to cause asbestosis/pulmonary fibrosis, pleural inflammation and thickening. This was a less important factor in my analysis.

## 4. Temporality:

Exposure to a substance must precede onset of disease for it to be causal. The above-described case-control and cohort studies had the objective of assessing talc exposure that preceded the onset of disease. In cohort studies, the exposure data was obtained before any women were diagnosed with ovarian cancer. In the case-control studies, women with ovarian cancer reported exposures prior to their diagnosis and controls reported exposures in the same time frame. In many studies the exposures went back several decades, providing even more assurance that the temporality requirement is met. This was an important factor in my analysis.

## 5. Biological gradient:

A biologic gradient, or dose-response, refers to an increased exposure corresponding to an increased risk. In the case of talc exposure, dose-response would ideally include both frequency of use and duration of use, or “application years” (total lifetime applications) similar to “pack-years” used in the setting of smoking. However, application-years is much more difficult to assess than pack-years, since one cannot easily quantify the amount of talc

used during each perineal application (unlike in smoking, where one can easily count the number of cigarettes smoked to calculate pack-years). Yet, when studies have evaluated duration and frequency of perineal talc use, most have found an increased risk of ovarian cancer with increased exposure (Harlow 1992, Cramer 1999, Mills 2004, Merritt 2008, Wu 2009, Terry 2013, Penninkilampi 2018). In the case of asbestos and mesothelioma, a study published by Plato et al. in 2018 found “a significant, dose–response relationship between maximum intensity asbestos exposure and mesothelioma of the pleura and cumulative asbestos exposure with 30-, 40-, and 50-years lag time. Cumulative exposure to asbestos, even at low levels, entailed an increased risk of mesothelioma of the pleura, indicating that even short periods with cumulative doses <1.78 f-y/ml can increase the risk of mesothelioma. Time since first exposure did not show any sufficient dose–response relationship in the longest lag period (>50 years).” (Plato 2018)

While there is evidence of a dose response, this data is more equivocal because of the challenge in measuring and comparing the extent of talcum powder usage. The evidence of biological gradient for talcum powder products is therefore very difficult to study. The evidence of biological gradient supports cause and effect, but for the reasons noted, it is limited by difficulties in the measurement of exposure. This was an important factor in my analysis.

#### 6. Plausibility:

In this context, plausibility means that an association can be explained by and is consistent with existing scientific knowledge and, in particular, that there is a biologically plausible explanation for the exposure (to talc) as a cause of ovarian cancer. Thus, plausibility is dependent upon the current state of scientific knowledge regarding a mechanism of disease. Hill noted plausibility is helpful but limited by current knowledge.

There is evidence that validates the biological plausibility of talc-related ovarian cancer. It is generally accepted that inflammation plays a role in carcinogenesis. Pelvic inflammatory disease and endometriosis are known risk factors for ovarian cancer, and they cause the release of inflammatory mediators. Talc is known to produce an inflammatory reaction, and is in fact used in clinical practice to induce inflammation in the pleura to treat patients with pneumothorax and pleural effusions. It has also been demonstrated that particles, including talc, can migrate proximally through the female genital tract and gain access to the perineum, ovaries, and fallopian tubes. Thus, it is plausible that talc can reach the ovaries and fallopian tubes and cause a proinflammatory reaction, including induction of cytokines and ROS that play a role in the onset of ovarian cancer. Other plausible mechanisms include a down-regulated immune response to MUC1, causing an immune tolerance of a MUC1-expressing cancer, and talc-induced macrophage TNF- $\alpha$  expression and subsequent ovarian tumorigenesis. The 2008 Gates study showed an association of talc and ovarian cancer in women with the GSTT1-null genotype (p-interaction=0.03), particularly in combination with the GSTM1-present genotype (p-interaction=0.03). It is thus plausible that women with a GSTT1-null phenotype are unable to eliminate talc as efficiently and are at increased risk of ovarian cancer. It is also highly plausible that asbestos in asbestos-tainted talc also releases cytokines and mutagenic ROS from inflammatory cells.



In the case of asbestos, fiber surface reactivity with free radical generation has been accepted as a mechanism of carcinogenesis (IARC Monograph). Asbestos-derived free radicals can lead to a variety of effects on cells including lipid peroxidation, DNA oxidation, TNF release, cell apoptosis, and increased uptake of asbestos fibers (Mossman 1983, Hobson 1990, Ghio 1998, Churg 1998, Gulumian 1999, Aust 1999, Upadhyay 2003, IARC Monograph). Asbestos fibers may directly cause the generation of ROS (IOM 2006) and indirectly cause ROS by inducing inflammation and macrophage activation (IARC Monograph). As noted above, the carcinogenicity of the other constituents of talc (cobalt, chromium, nickel, and fragrance ingredients) adds strength to biologic plausibility.

This biologic evidence, provides a biologically plausible explanation for the increased risk seen in the epidemiologic studies and is therefore a very strong factor in favor of a cause and effect relationship.

#### 7. Coherence:

Coherence in this context means coherence between epidemiological and generally accepted knowledge of the disease in question. Numerous studies addressing talc use and ovarian cancer have indicated talc use increases ovarian cancer risk consistently. The coherence of the epidemiological evidence linking a risk of ovarian cancer with talc use, in tandem with biologically plausible mechanistic evidence discussed above, is striking and weighs heavily in support of causation.

#### 8. Experiment:

Hill suggested that evidence drawn from experimental manipulation, particularly epidemiologic studies in which disease risk declines following an intervention or cessation of exposure, may lead to the strongest support for causal association. No studies exist that follow women after cessation of genital powder use and assess them specifically for a change in risk of ovarian cancer. The challenge of such a study is that it has been shown that talc-associated ovarian cancer takes years or decades before onset of disease. However, the Australian study performed by The Survey of Women's Health Study Group published in 1997 found that the risk of ovarian cancer was highest among women who were talc users and had not undergone surgical sterilization (RR=1.3, CI 1.1-1.6). (Green 1997). This indicates that tubal ligation or hysterectomy, by impeding the proximal migration of talc into the perineum to the ovaries and fallopian tubes, decreases the risk of talc-associated ovarian cancer, lending support to Hill's experiment aspect in the context of talc and ovarian cancer.

There are experimental studies in the literature that support a causal relationship between talc and ovarian cancer. Examples include studies that show increases in inflammatory markers following talc exposure (Allaire 1989, Genofre 2009, Arellano-Orden 2013). There is also evidence that talc causes neoplastic transformation in ovarian cells (Buz'Zard 2007) and that talc induces genotoxicity in mesothelial cells (Shukla 2009). Additionally, there is evidence that talc induces macrophage TNF- $\alpha$  expression (Cheng 2000), and macrophages that express TNF- $\alpha$  have been shown to promote ovarian tumorigenesis

(Hagemann 2006). Of note, invasive serous carcinomas commonly have p53 mutations and TNF- $\alpha$  induced chromosomal mutations have been shown to occur mostly in cells with p53 aberrations (Yan 2006).

It has long been generally accepted that asbestos exposure causes mesothelioma, ovarian cancer, and lung cancer (Dement 1994, deKlerk 1996, Berry 2000, IARC 2012). The experimental evidence was very important to my analysis.

#### 9. Analogy:

Comparisons of similar associations can be used to determine plausibility. Hill suggested that when there is strong evidence of a causal relationship between a particular agent and a specific disease, researchers should be more accepting of weaker evidence that a similar agent may cause a similar disease. Analogy under the Bradford Hill viewpoints has been interpreted to mean that when one causal agent is known, the standards of evidence are lowered for a second causal agent that is similar in some way (Susser 1991). In the case of talc and ovarian cancer, one can use the analogy of asbestos and mesothelioma. Both talc and asbestos are silicates, and asbestos causes an inflammatory and fibrosing reaction within the pleura, which is generally accepted to be the primary cause of mesothelioma years later. It is the inflammatory and fibrosing reaction caused by talc that has led to its common use in the treatment of pneumothorax and pleural effusions by injection into the pleural cavity. Similarly, in the case of asbestos, fiber surface reactivity with free radical generation has been accepted as a mechanism of carcinogenesis (IARC Monograph). The analogy evidence was somewhat important in my analysis.

### XVII. CONCLUSION:

Based upon the totality of the evidence and consideration of the Bradford Hill viewpoints, which includes the high consistency and replication of the findings in the epidemiological studies, pathological, biological, and mechanistic evidence, it is my opinion, which I hold to a reasonable degree of scientific and medical certainty, that genital talcum powder exposure can cause ovarian cancer.



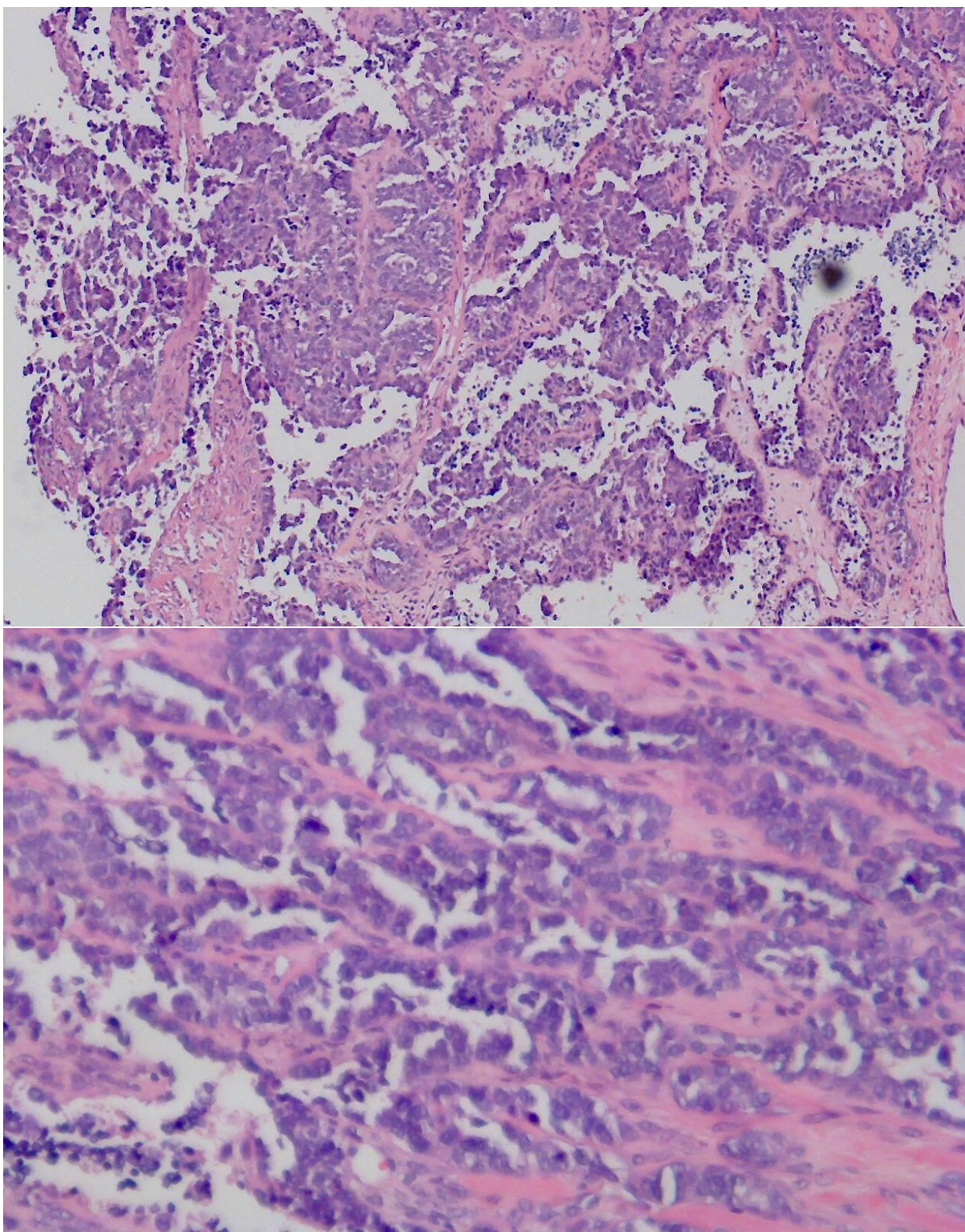


Figure 1. Ovarian invasive serous carcinoma.



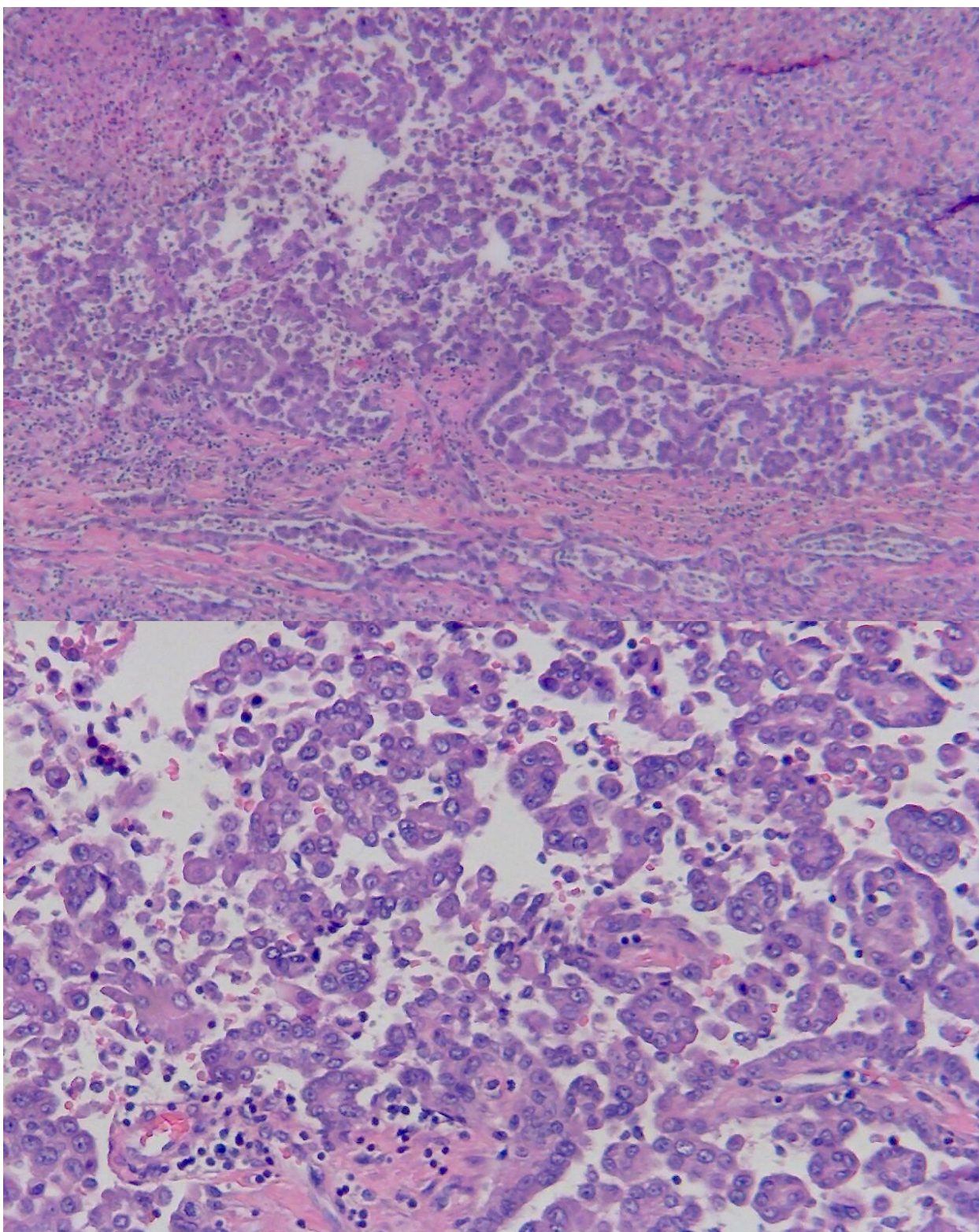


Figure 2. Mesothelioma. Notice the morphologic similarities to ovarian serous carcinoma (Fig 1).



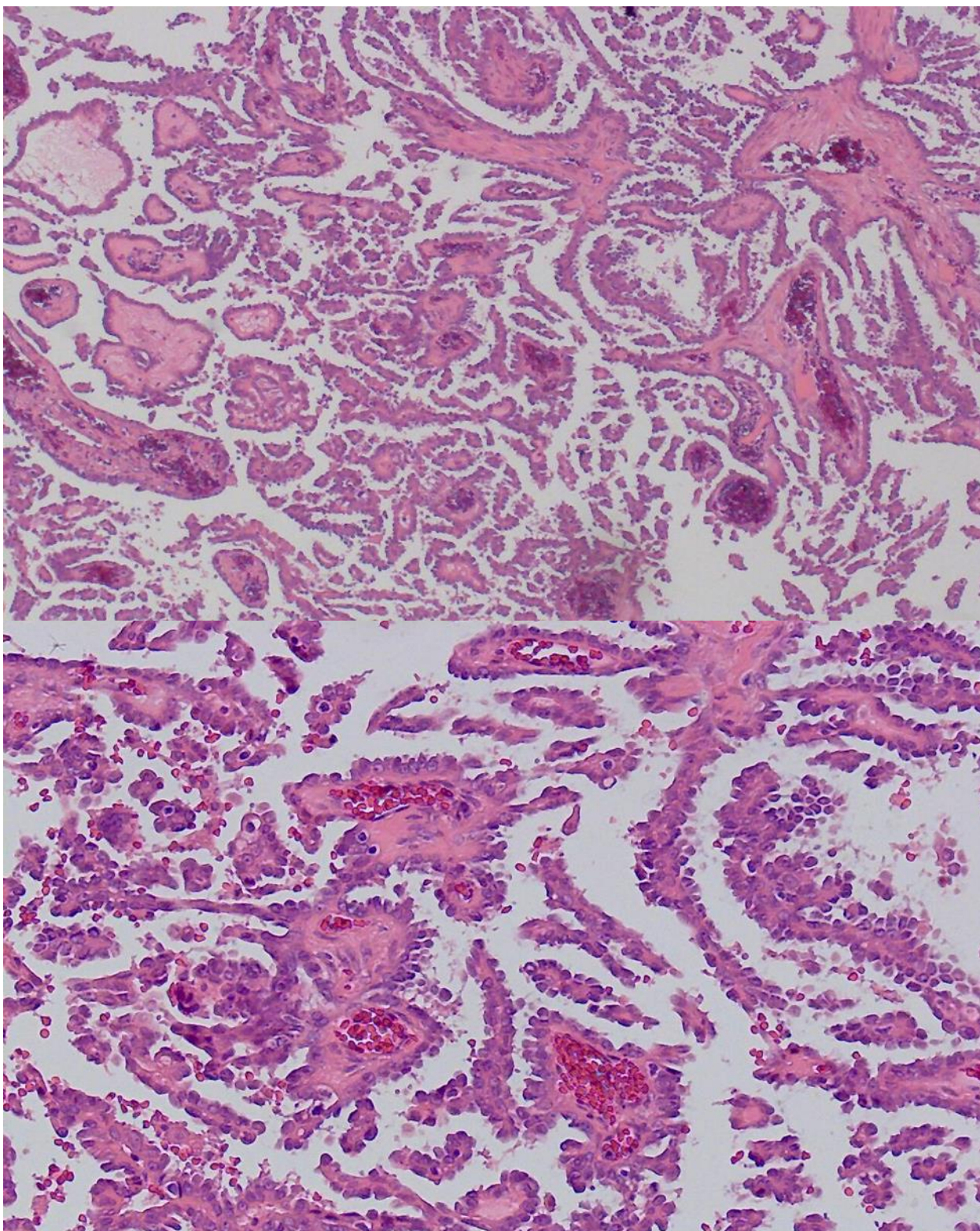


Figure 3. Ovarian serous borderline tumor.



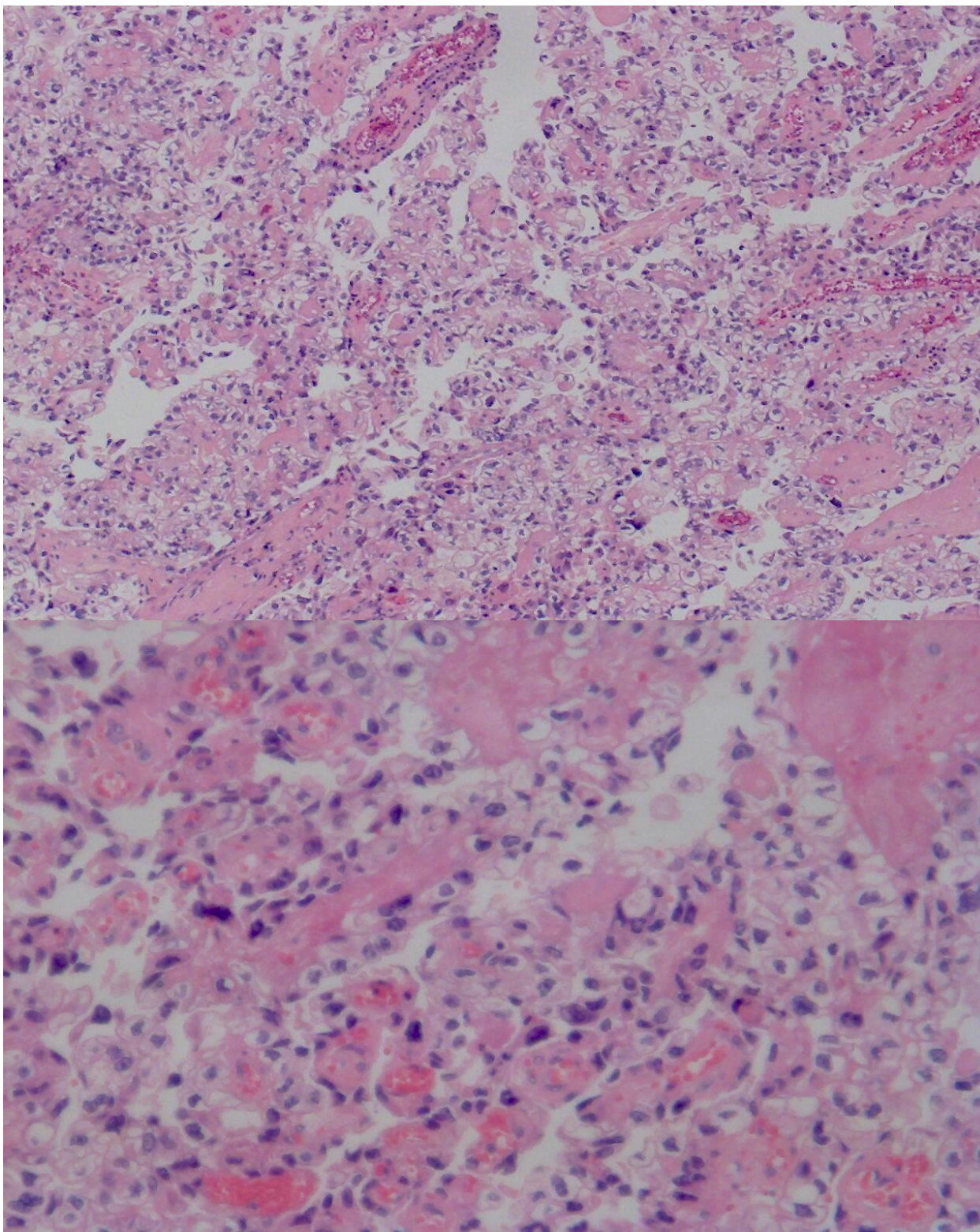


Figure 4. Ovarian clear cell carcinoma.



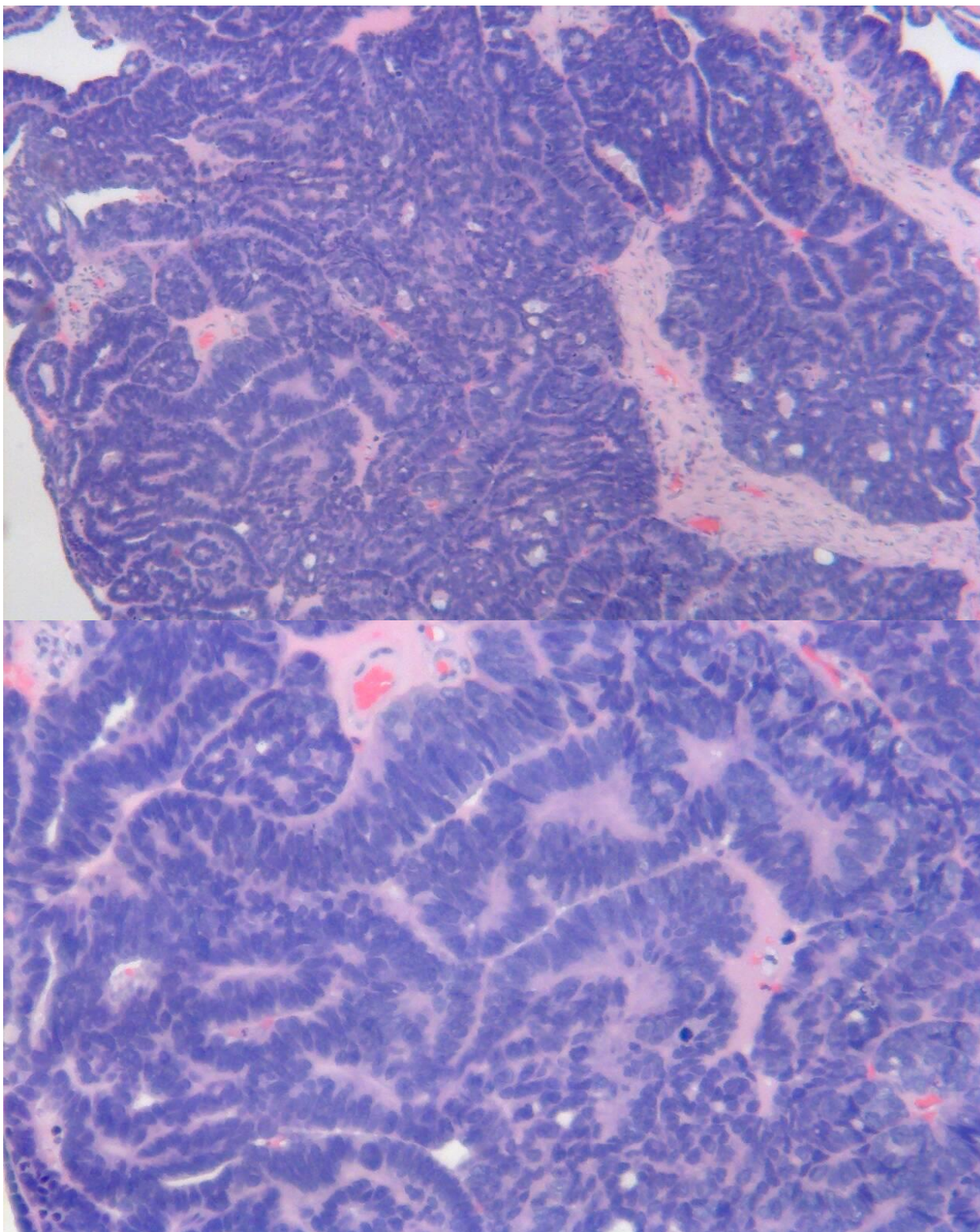


Figure 5. Ovarian endometrioid carcinoma.



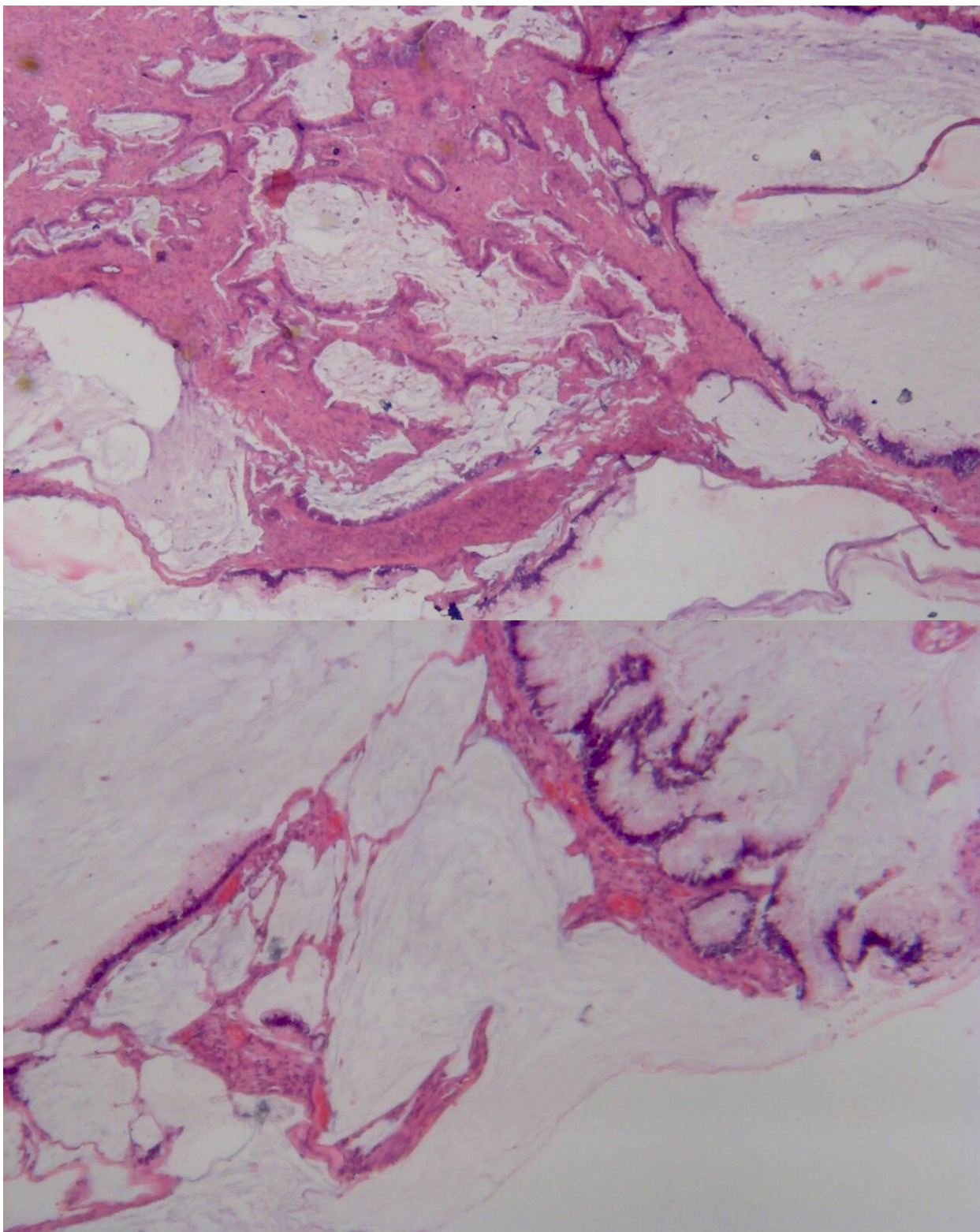


Figure 6. Ovarian mucinous carcinoma.

**EXHIBIT A**

## CURRICULUM VITAE

Date prepared: January 2018

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Home E-Mail: [sarahkane898@gmail.com](mailto:sarahkane898@gmail.com)

Place of Birth: Norwalk, CT

### Education:

1995	B.A.	Skidmore College Cum laude
2001	M.D.	The Ohio State University College of Medicine

### Postdoctoral Training:

2001-2005	Resident	Pathology, AP/CP	Massachusetts General Hospital
2005-2007	Fellow	Robert E. Scully Fellow	Massachusetts General Hospital
		Cytopathology, Gynecologic and Perinatal Pathology	

### Academic Appointments:

2001-2005	Clinical Instructor	Pathology	Harvard Medical School
2005-2007	Graduate Assistant	Pathology	Harvard Medical School
2007-2011	Instructor	Pathology	Harvard Medical School

### Appointments at Hospitals/Affiliated Institutions

2007-2011	Staff Pathologist	Pathology	Beth Israel Deaconess
2007-2011	Staff Pathologist	Pathology	Beth Israel Deaconess-Needham
2011-Present	Staff Pathologist	Pathology	North Shore Medical Center
2011-Present	Staff Pathologist	Pathology	Newton-Wellesley Hospital
2011-Present	Clinical Affiliate	Pathology	Massachusetts General Hospital

#### Major Administrative Responsibilities:

2005	Chief Resident, Anatomic Pathology	Massachusetts General Hospital
2007-2011	Course Director, PA501.5 Elective	Harvard Medical School
2010-2011	Associate Director, Cytopathology Fellowship	BIDMC/Harvard
2012-2013	Hematology Laboratory Director NSMC	NSMC/Partners
2013-Present	Autopsy Director, North Shore Medical Center	NSMC/Partners

#### Major Committee Assignments:

2005-2007	Cytopathology	Junior Member	College of American Pathologists
2005	Path Residency Training Committee	Member	Massachusetts General Hospital
2005	Anatomic Path Quality Assurance	Member	Massachusetts General Hospital
2005	Anatomic Path Steering Committee	Member	Massachusetts General Hospital
2008-2011	Path Resident Selection Committee	Member	Beth Israel Deaconess
2009-2011	Path Residency Planning Committee	Member	Beth Israel Deaconess
2010	Pathology Scheduling Committee	Member	Beth Israel Deaconess
2010-2011	Anatomic Path Quality Assurance	Member	Beth Israel Deaconess

#### Professional Societies:

1997 – 2001	American Medical Student Association	Member
2001 – Present	Massachusetts Medical Society	Member
2003 – Present	United States and Canadian Academy of Pathology	Member
2005 - Present	College of American Pathologists	Member

#### Awards and Honors:

1994	Charlotte W. Fahey Prize in Chemistry, Skidmore College
1994	Skidmore College Periclean Honor Society
1995	Phi Beta Kappa, Skidmore College
1995	Cum Laude with Department Honors, Skidmore College
2000	Honors in Pediatric Hematology and Oncology 4th Year Clerkship
2000	Letter of Commendation, Surgery Third Year Clerkship
2000	Letter of Commendation, Neurology Third Year Clerkship
2001	Honors in Anatomic and Clinical Pathology Fourth Year Elective
2001	Honors in Individual Studies in Pathology Fourth Year Elective
2016	Partners in Excellence Team Award

#### Teaching of Students:

##### Harvard Medical School Courses:

2007-2009	Respiratory Pathophysiology
2 <sup>nd</sup> Year Medical Students	Lab Instructor      Three 2 hour sessions, one week

2007-2009	Cardiovascular Pathophysiology	
2 <sup>nd</sup> Year Medical Students	Lab Instructor	Three 2 hour sessions, one week
2007-2011	Core Surgery Clerkship	
3 <sup>rd</sup> Year Medical Students	Pathology Coordinator	One hour lecture/3 months
2009-2011	Principal Clinical Experience	
3 <sup>rd</sup> Year Medical Students	Mentor	Two hour session per week
2009-2011	Principal Clinical Experience – Pathology Elective	
3 <sup>rd</sup> Year Medical Students	Mentor	Minimum 2 hour session/month

Formal Teaching of Residents:

2007	Respiratory Cytology	
All pathology residents	Beth Israel Deaconess	One hour lecture
2007-2011	Respiratory Cytology	Quarterly 1 hr microscope session
Pathology residents rotating through Cytology		
2008-2011	Fine Needle Aspiration Techniques	
All pathology residents	Beth Israel Deaconess	One hour lecture
2008-2011	Histologic and Cytologic Correlation of Cervical Lesions	
All pathology residents	Beth Israel Deaconess	One hour lecture

Clinical Supervisory and Training Responsibilities:

2007-2011 Core Surgery Clerkship, Pathology Elective BIDMC 2 students/month

Local Invited Presentations:

2005 Cytology/Histology Correlation Clinical Pathology Technician Lecture Series  
Department of Pathology, Massachusetts General Hospital

2008 Respiratory Cytology Cytopathology Lecture Series  
Department of Pathology, Brigham and Women's Hospital

Current Licensure and Certification:

2005 Full License, Massachusetts

2008 Board certified, Anatomic and Clinical Pathology

2008 Board certified, Cytopathology



Practice Activities:

Surgical Pathology, Cytopathology, Autopsy	North Shore Medical Center
Surgical Pathology, Cytopathology	MGH Ambulatory Care Center
Cytopathology	Massachusetts General Hospital
Clinical Pathology	Newton-Wellesley Hospital

Peer-Reviewed Publications:

Narasimhan V, Malboueuf B, **Hodil SE**. Temperature Induced Interstrand Crosslinks in Cisplatin-DNA Adducts Detected by Electrophoresis and UV Spectrophotometer. *Biochem Mol Biol Int*. 1995;37:843-851.

Grundy FJ, Hodil SE, **Rollins SM**, Henkin TM. Specificity of tRNA-mRNA Interactions in *Bacillus subtilis* tyrS antitermination. *J Bacteriol*. 1997;179:2587-2594.

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Chan MP, Hecht JL, **Kane SE**. Clinicopathologic Correlation of Fetal Vessel Thrombosis in Mono- and Dichorionic Twin Placentas. *J Perinatol*. 2010 Oct; 30(10):660-4.

**Kane SE**, Hecht JL. Endometrial Intraepithelial Neoplasia Terminology in Practice: 4-Year Experience at a Single Institution. *Int J Gynecol Cancer*. 2012 Mar;31(2):160-165.

Haspel RA, Bhargava P, Gilmore H, **Kane SE**, Powers A, Sepehr A, Weinstein A, Schwartzstein R, Roberts D. Successful Implementation of a Longitudinal, Intergrated Pathology Curriculum During the Third Year of Medical School. *Arch Pathol Lab Med*. 2012 Nov;136(11):1430-6.

Proceedings of Meetings (Poster Presentations):

**Rollins S**, Prayson RA, McMahon JT, Cohen BH. Diagnostic Yield of Muscle Biopsy in Patients With Clinical Evidence of Mitochondrial Cytopathy. 90th United States and Canadian Academy of Pathology. March 2001. Atlanta, GA.

**Rollins SE**, Nielsen GP, Hedley-Whyte ET. Light Microscopy, Electron Microscopy, and Mitochondrial Enzyme Function in Muscle Biopsies for Suspected Mitochondrial Cytopathies. 92<sup>nd</sup> United States and Canadian Academy of Pathology. March 2003. Washington, DC.

**Rollins SE**, Nielsen GP, Hedley-Whyte ET. Light Microscopy, Electron Microscopy, and Mitochondrial Enzyme Function in Muscle Biopsies for Suspected Mitochondrial Cytopathies. Massachusetts General Hospital Clinical Research Day. June 2003. Boston, MA.

**Rollins SE**, Young RH, Bell DA. Autoimplants Involving Serous Borderline Tumors of the Ovary: A Clinicopathologic Study of 30 Cases. 93<sup>rd</sup> United States and Canadian Academy of Pathology. March 2004. Vancouver, BC.

Michaels PJ, **Rollins SE**, Bounds BC, Brugge WR, Pitman MB. Cyst Fluid Analysis and Endoscopic Features Aid in the Preoperative Grading of Intraductal Papillary Mucinous Neoplasms of the Pancreas. 95<sup>th</sup> United States and Canadian Academy of Pathology. February 2006. Atlanta, GA.

**Rollins SE**, Clement PB, Young RH. Uterine Tumors Resembling Ovarian Sex Cord Tumors Frequently Have Incorporated Mature Smooth Muscle Imparting a Pseudoinfiltrative Appearance. 96<sup>th</sup> United States and Canadian Academy of Pathology, March 2007. San Diego, CA.

White SR, Hecht J, **Kane SE**, Fu Y, Cohen DW, Wang HH. Bile duct brush cytology: indeterminate diagnosis is essential. Arch Pathol Lab Med 2009;133:1689.

**EXHIBIT B**

## SARAH E. KANE, M.D.

Board Certified in Anatomic and Clinical Pathology, and Cytopathology

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### REFERENCES CITED AND OTHER MATERIAL AND DATA CONSIDERED

#### LITERATURE:

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# Exhibit 11

Sarah E. Kane, M.D.

Page 1

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

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IN RE: JOHNSON & JOHNSON TALCUM

POWDER PRODUCTS MARKETING, SALES

PRACTICES, AND PRODUCTS

MDL NO:

LIABILITY LITIGATION

16-2738 (FLW)(LHG)

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THIS DOCUMENT RELATES TO

ALL CASES

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DEPOSITION UNDER ORAL EXAMINATION OF

SARAH E. KANE, M.D.

January 25, 2019, 9:19 a.m.

- - -

REPORTED BY: JANET M. SAMBATARO, RMR, CRR, CLR

- - -

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Sarah E. Kane, M.D.

<p style="text-align: right;">Page 2</p> <p>1 2 3 4 5 6 7 Deposition of SARAHE. KANE, M.D., 8 held at the offices of Sugarman, Rogers, 9 Barshak &amp; Cohen, PC 363 Plantation Street, Boston, 10 Massachusetts, pursuant to Agreement before 11 Janet Sambataro, a Registered Merit Reporter, 12 Certified Realtime Reporter, Certified LiveNote 13 Reporter, and a Notary Public within and for the 14 Commonwealth of Massachusetts, on January 25, 2019, 15 commencing at 9:19 a.m. 16 17 18 19 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 4</p> <p>1 APPEARANCES: (Continued) 2 3 SHOOK, HARDY &amp; BACON L.L.P. 4 BY: HUNTER K. AHERN, ESQ. 5 701 Fifth Avenue, Suite 6800 6 Seattle, Washington 98104 7 (206) 344-7600 8 hahern@shb.com 9 Representing the Defendant, Johnson &amp; Johnson, 10 Johnson &amp; Johnson Consumer Companies, Inc. 11 12 DRINKER BIDDLE AND REATH LLP 13 BY: KATHERINE MCBETH, ESQ. 14 One Logan Square, Suite 2000 15 Philadelphia, Pennsylvania 19103-6996 16 (215) 988-2700 17 katherine.mcbeth@dbr.com 18 Representing the Defendant, Johnson &amp; Johnson, 19 Johnson &amp; Johnson Consumer Companies, Inc. 20 21 GORDON &amp; REES SCULLY MANSUKHANI, LLP 22 BY: MICHAEL R. KLATT, ESQUIRE 23 816 Congress Avenue, Suite 1510 24 Austin, Texas 78701 25 (512) 391-0197</p>
<p style="text-align: right;">Page 3</p> <p>1 APPEARANCES: 2 HAUSFELD LLP 3 BY: STEVE ROTMAN, ESQ. 4 One Marina Park Drive 5 Suite 1410 6 Boston, MA 02210 7 (617) 207-0600 8 srotman@hausfeld.com 9 Representing the Plaintiffs 10 11 LEVIN PAPANTONIO 12 BY: CHRISTOPHER V. TISI, ESQ. 13 316 South Baylen St. 14 Pensacola, Florida 32502 15 (850) 435-7000 16 ctisi@levinlaw.com 17 Representing the Plaintiffs 18 19 RESTAINO LAW, LLC 20 BY: JOHN RESTAINO, ESQ. 21 130 Forest Street 22 Denver, Colorado 80220 23 (303) 839-8000 24 JRestaino@RestainoLLC.com 25 Representing the Plaintiffs</p>	<p style="text-align: right;">Page 5</p> <p>1 APPEARANCES: (Continued) 2 3 GORDON &amp; REES SCULLY MANSUKHANI, LLP (Continued) 4 Representing the Defendants, 5 Imerys Talc America, Inc. 6 7 8 COUGHLIN DUFFY LLP 9 BY: AMARYAM M. MESEHA, ESQ. 10 350 Mount Kemble Avenue 11 Morristown, New Jersey 07962 12 (973) 267-0058 13 mmeseha@coughlinduffy.com 14 Representing Imerys Talc America, Inc. 15 16 17 TUCKER ELLIS LLP 18 BY: MICHAEL ANDERTON, ESQ. 19 950 Main Avenue 20 Cleveland, Ohio 44113 21 (216) 592-5000 22 michael.anderton@tuckerellis.com 23 Representing PTI 24 25 - Continued -</p>

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1 APPEARANCES: (Continued)	1 E X H I B I T S
2	2 Number Description Page
3 SEYFARTH SHAW LLP	3 Exhibit 9 Article entitled "Serous tubal
4 BY: THOMAS T. LOCKE, ESQ. (Via telephone)	4 intraepithelial carcinoma, chronic
5 975 F Street, N.W.	5 fallopian tube injury, and serous
6 Washington, D.C. 20004	6 carcinoma development" 91
7 (202) 463-2400	7 Exhibit 10 "Blaustein's Pathology of the Female
8 Representing PCPC	8 Genital Tract," Fourth Edition 95
9	9 Exhibit 11 Excerpt from "Blaustein's Pathology of
10 ALSO PRESENT:	10 the Female Genital Tract,"
11 Jody Urbati, Videographer	11 Fourth Edition 98
12	12 Exhibit 12 Blaustein's Pathology of the Female
13	13 Genital Tract" 160
14	14 Exhibit 13 Excerpt of "Blaustein's Pathology
15	15 of the Female Genital Tract, Fifth
16	16 Edition 160
17	17 Exhibit 14 Rule 26 Expert Report of Sarah E.
18	18 Kane, M.D. 164
19	19 Exhibit 15 Document entitled "References Cited
20	20 and Other Material and Data
21	21 Considered" 165
22	22 Exhibit 16 Document entitled "Additional
23	23 Material Considered" 181
24	24 Exhibit 17 Document entitled "Additional Materials
25	25 to Dr. Sarah Kane" 186
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1 I N D E X	1 E X H I B I T S
2 WITNESS DIRECT CROSS REDIRECT RECROSS	2 Number Description Page
3 SARAH E. KANE, M.D.	3 Exhibit 18 "The Plaintiffs' Steering Committee's
4 By Ms. Ahern 15	4 Initial Designation and Disclosure of
5 By Mr. Klatt 318 348	5 Non-case Specific Expert Witnesses" 194
6 By Mr. Rotman 341	6 Exhibit 19 Article entitled "Presence of Talc
7	7 in Pelvic Lymph Nodes of a Woman with
8 E X H I B I T S	8 Ovarian Cancer and Long-Term Genital
9 Number Description Page	9 Exposure to Cosmetic Talc" 252
10 Exhibit 1 Notice of Oral and Videotaped	10 Exhibit 20 Article entitled "Perineal Exposure
11 Deposition of Sarah E. Kane and	11 to Talc and Ovarian Cancer Risk" 260
12 Duces Tecum 27	12 Exhibit 21 Article entitled "Genital Talc
13 Exhibit 2 Curriculum vitae of Sarah E.	13 Exposure and Risk of Ovarian Cancer" 266
14 Kane, M.D. 29	14 Exhibit 22 Article entitled "Perineal Talc
15 Exhibit 3 Invoice from Sarah Kane, M.D., for	15 Exposure and Epithelial Ovarian Cancer
16 services 5/19 through 7/14 31	16 Risk in the Central Valley of
17 Exhibit 4 Invoice from Sarah Kane, M.D., for	17 California" 272
18 services 7/28 through 9/12 41	18 Exhibit 23 Highlighted copy of Dr. Kane's
19 Exhibit 5 Invoice from Sarah Kane, M.D., for	19 expert report 284
20 services 9/18/17 through 2/5/18 43	20 Exhibit 24 Article entitled "Talcum powder,
21 Exhibit 6 Invoice from Sarah Kane, M.D., for	21 chronic pelvic inflammation and
22 services 2/23/18 through 8/3/18 44	22 NSAIDs in relation to risk of
23 Exhibit 7 Invoice from Sarah Kane, M.D., for	23 epithelial ovarian cancer" 289
24 services 9/20/18 through 11/16/18 45	24 Exhibit 25 Article entitled "The relationship
25 Exhibit 8 Excerpt from Blaustein's Second Edition 54	25 between perineal cosmetic talc usage

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1	EXHIBITS		1	identified yesterday in that list are voluminous	
2	Number	Description	2	and dense and require additional time to cover,	
3	Exhibit 25 (Continued)	Page	3	to the extent that they substantively informed	
4			4	Dr. Kane's opinions in this case.	
5	Exhibit 26 Article entitled "Pycnogenol reduces	308	5	We'd also like to object to the	
6	Talc-induced Neoplastic Transformation		6	inclusion of those materials on the science day	
7	in Human Ovarian Cell Cultures"	328	7	presentations, which were not intended for any	
8			8	other purpose than for science day in the MDL.	
9			9	And that's all I have to say on the	
10			10	objections.	
11			11	MR. ROTMAN: Go ahead.	
12			12	MR. TISI: First of all, as you know,	
13			13	many of those documents were documents that were	
14			14	provided to counsel in connection with virtually	
15			15	every depositions that have been taken to date.	
16			16	In fact, it was provided with Dr. Mohrman that	
17			17	was being taken at the same time today; it was	
18			18	provided with Dr. Zelikoff earlier in the week;	
19			19	it was provided almost routinely.	
20			20	Many of them -- some of them,	
21			21	particularly the Health Canada document, were	
22			22	documents that only became available in mid	
23			23	December, number one.	
24			24	Number two, I believe that the science	
25			25	day document that you're referring to, which I	

Page 11			Page 13		
1	PROCEEDINGS		1	think you'll find was not relied on in any way,	
2	THE VIDEOGRAPHER: We are now on the		2	was a -- that was the California and not the MDL.	
3	record. My name is Jody Urbati. I am a		3	So I just want to be clear about that.	
4	videographer for Golkow Litigation Services.		4	So there is no prejudice, and we would	
5	Today's date is January 25, 2019; the time,		5	clearly object to -- these are not documents she	
6	9:19 a.m.		6	relied on for her report; they just are	
7	This video deposition is being held in		7	supplemental materials. But -- you can ask	
8	Boston, Massachusetts, In Re: Johnson & Johnson		8	questions, but we will certainly object to	
9	Talcum Powder Products Liability Litigation in		9	reconvening the deposition at any later time. We	
10	the United States District Court for the District		10	made that clear yesterday.	
11	of New Jersey.		11	MS. AHERN: Thank you.	
12	The deponent today is Sarah Kane.		12	MR. ROTMAN: Yeah, there was -- one of	
13	Counsel will be noted on the stenographic record.		13	the documents was a textbook that Dr. Kane first	
14	The court reporter is Janet Sambataro and will		14	looked at two days ago or -- yeah, I think it was	
15	now swear in the witness.		15	two days ago, and so I added it to the list. And	
16	(Witness sworn.)		16	she brought the textbook with her today.	
17	MS. AHERN: Just a quick housekeeping		17	MR. KLATT: Can I just add we had an	
18	matter. The defendants would like to lodge an		18	agreement for all the other depositions, and I	
19	objection to the additional materials to Sarah		19	assume we continue today, one objection by a	
20	Kane that were served yesterday at 3:36 p.m. by		20	party is good for all.	
21	Ashcraft law firm. Serving supplementary		21	MR. TISI: That's fine, yes.	
22	materials 24 hours before an expert deposition is		22	MR. ROTMAN: And, you know, just so	
23	prejudicial to the defendants' ability to		23	it's clear to anybody reading the transcript that	
24	prepare.		24	what you received yesterday was the third	
25	The number of the documents that were		25	reference list that we've provided for Dr. Kane,	

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<p>1 the first being with her report in November; the 2 second being on January 4th, which was about ten 3 days before the deposition had been scheduled for 4 January 14th; and then these additional items 5 were materials that either were inadvertently 6 left off or not reviewed until just very 7 recently. 8 MS. AHERN: Okay. To the extent that 9 these new materials inform her substantive 10 opinions and were not included in her report or 11 prior versions of the reference list, then we can 12 talk about that later -- 13 MR. TISI: Yeah. 14 MS. AHERN: -- in terms of additional 15 time. 16 And just to clarify, Steve, you said 17 that she reviewed one textbook. It looks like on 18 the list that I received, she reviewed the 19 second, fourth, and fifth editions of the 20 textbook -- 21 MR. ROTMAN: I was referring -- 22 MS. AHERN: -- or textbooks. 23 MR. ROTMAN: I was referring to that as 24 one textbook, yeah, but you're right, the 25 different editions. And she did bring with her</p>	<p>1 Commonwealth Pathology Partners? 2 A. The address we commonly use is 81 3 Highland Avenue, Salem, Massachusetts. It's 4 01970. 5 Q. Okay. And do you have any separate 6 consulting business? 7 A. No. Other -- outside of this type of 8 medical expert witness work, no. 9 Q. Okay. And how often do you do this 10 sort of medical witness work? 11 A. I am very new at it. I have done one 12 deposition before in a tobacco case. 13 Q. Okay. And the fees that you get from 14 these cases, do they go directly to you or do 15 they go to your -- Commonwealth Pathology 16 Partners? 17 A. They go directly to me. 18 Q. And, Dr. Kane, you're a medical doctor; 19 correct? 20 A. Yes. 21 Q. And what is your medical specialty? 22 A. I am board certified in anatomic and 23 clinical pathology and cytopathology, with 24 fellowship training in gynecologic pathology. 25 Q. Does that mean that you review</p>
Page 15	Page 17
<p>1 today those materials. 2 MS. AHERN: So she has a copy with her 3 today of all of the items listed in the 4 additional materials to Sarah Kane that was 5 served yesterday. 6 MR. ROTMAN: No. 7 MS. AHERN: Okay. Do you know what 8 she -- well, we can -- we'll find out. 9 MR. ROTMAN: Yeah. 10 MS. AHERN: Okay. All right. 11 SARAH E. KANE, M.D., 12 having been duly sworn, after presenting 13 identification in the form of a driver's license, 14 deposes and says as follows: 15 DIRECT EXAMINATION 16 BY MS. AHERN: 17 Q. Good morning, Dr. Kane. 18 A. Good morning. 19 Q. Can you please state your name for the 20 record? 21 A. Sure. Sarah Kane. 22 Q. And, Dr. Kane, who is your current 23 employer? 24 A. Commonwealth Pathology Partners. 25 Q. And do you have a business address at</p>	<p>1 diagnostic materials, slides, and blocks that 2 have been taken from patient procedures and make 3 determinations regarding diagnosis? 4 A. Yes. 5 Q. Do you see patients as part of your 6 medical practice? 7 A. Yes. Occasionally, cytopathologists 8 sometimes perform a procedure that's called a 9 fine-needle aspiration. And so if a patient is 10 seen in clinic and the clinician discovers a 11 palpable nodule, I might be asked to go into the 12 room and perform a fine-needle aspiration. 13 Q. But you don't see patients in the sense 14 that you don't counsel patients and provide 15 ongoing care for an individual patient? 16 A. Well, I mean, I guess my pathology 17 report is part of the -- basically speaks to 18 medical treatment and informs clinical treatment 19 of the patient. So my pathology reports are seen 20 by the patient. 21 Q. I guess what I'm getting at is: Do you 22 see patients as part of your practice, give them 23 a history and physical, provide ongoing care for 24 them outside of the setting of a fine-needle 25 aspiration or a specific procedure related to a</p>

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<p>1 diagnosis?</p> <p>2 MR. ROTMAN: Is this working for you?</p> <p>3 THE WITNESS: Oh, I'm sorry?</p> <p>4 MR. ROTMAN: Is it working?</p> <p>5 THE WITNESS: Yes.</p> <p>6 MR. ROTMAN: Okay.</p> <p>7 A. Outside of the fine-needle aspiration</p> <p>8 setting, the only time I might see a patient</p> <p>9 would be with a blood transfusion reaction. I</p> <p>10 might have to go to the floor to examine the</p> <p>11 patient or patient chart.</p> <p>12 Ongoing care for them outside of the setting</p> <p>13 of a fine-needle aspiration, the nature of</p> <p>14 gynecologic pathology, sometimes I will see a Pap</p> <p>15 smear from a patient and then a cervical biopsy</p> <p>16 from a patient and then a LEEP from the patient,</p> <p>17 and I might speak to the clinician about</p> <p>18 treatment algorithms, that kind of thing.</p> <p>19 Q. Do you actually then go see the patient</p> <p>20 themselves and discuss with them the results of</p> <p>21 their Pap smear or other testing?</p> <p>22 A. Typically, no.</p> <p>23 Q. Have you ever performed a history and</p> <p>24 physical in your practice as a pathologist?</p> <p>25 A. Yes.</p>	<p>1 aspiration, a blood transfusion reaction.</p> <p>2 Are there any others?</p> <p>3 A. I'm trying to think what another</p> <p>4 possibility might be.</p> <p>5 I mean, I go into the operative room when</p> <p>6 patients are in surgery sometimes with the</p> <p>7 surgeon to do intraoperative frozen sections,</p> <p>8 which are realtime diagnosis while the patient is</p> <p>9 having a procedure.</p> <p>10 Q. But you're interacting with the</p> <p>11 physicians in that respect, aren't you, not with</p> <p>12 the patient?</p> <p>13 A. It can be both.</p> <p>14 MR. ROTMAN: Objection. Objection.</p> <p>15 You can answer.</p> <p>16 MS. AHERN: You can answer.</p> <p>17 A. The vast majority of the time I'm with</p> <p>18 frozen sections, I'm interacting with the</p> <p>19 surgeon.</p> <p>20 Q. Are there times where you are</p> <p>21 interacting with the patient during a surgical</p> <p>22 procedure?</p> <p>23 MR. ROTMAN: When you say</p> <p>24 "interacting," you mean having a conversation or</p> <p>25 do you mean having any kind of contact?</p>
Page 19	Page 21
<p>1 Q. Under what circumstances?</p> <p>2 A. Under blood transfusion reactions.</p> <p>3 Q. And what sort of history and physical</p> <p>4 do you take in relation to a blood transfusion</p> <p>5 reaction?</p> <p>6 A. Well, you might be looking at blood</p> <p>7 pressure and review of the medical chart,</p> <p>8 temperature, that kind of thing.</p> <p>9 Q. So you review the medical chart.</p> <p>10 Is that medical chart prepared by another</p> <p>11 physician?</p> <p>12 A. Usually, you're looking at</p> <p>13 retrospective data at the time of the blood</p> <p>14 transfusion reaction.</p> <p>15 Q. How often will you see the same patient</p> <p>16 who has had a blood transfusion reaction?</p> <p>17 A. Not very often.</p> <p>18 Q. Okay. Do you ever counsel patients on</p> <p>19 risk factors for ovarian cancer?</p> <p>20 A. Have I ever? Probably, but in my</p> <p>21 day-to-day practice, I'm not seeing patients on a</p> <p>22 regular basis to do that.</p> <p>23 Q. And the only time you see patients is</p> <p>24 with regard to specific issues that are within</p> <p>25 your realm of pathology expertise, a fine-needle</p>	<p>1 MR. KLATT: Steve, just limit the</p> <p>2 objection to "form."</p> <p>3 MR. ROTMAN: I'm trying to clarify.</p> <p>4 MR. KLATT: It doesn't matter.</p> <p>5 BY MS. AHERN:</p> <p>6 Q. Did you understand --</p> <p>7 MR. KLATT: Object to form.</p> <p>8 Q. -- the question, Doctor?</p> <p>9 A. Let me -- can -- I'm sorry. Can you</p> <p>10 read it back or --</p> <p>11 Q. You said, "The vast majority of" --</p> <p>12 MR. ROTMAN: She's reading, I think.</p> <p>13 MS. AHERN: I'll withdraw the question</p> <p>14 and just remind you.</p> <p>15 BY MS. AHERN:</p> <p>16 Q. You said that the vast majority of the</p> <p>17 time you're interacting with the physicians;</p> <p>18 correct?</p> <p>19 A. Yes.</p> <p>20 Q. What do you mean by "interacting"?</p> <p>21 A. During the surgery, the surgeon might</p> <p>22 have me come up to the operative room or the</p> <p>23 surgeon might come down to look at the tissue,</p> <p>24 both grossly and under the microscope with me.</p> <p>25 Q. Okay. Under those circumstances, would</p>

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<p>1 you ever speak to the patient?</p> <p>2 A. Usually not.</p> <p>3 Q. And if you -- have you ever spoken to a</p> <p>4 patient when you were reviewing frozen sections?</p> <p>5 A. I might have during rapid reads of</p> <p>6 fine-needle aspirations. So sometimes</p> <p>7 interventional radiologists will do fine-needle</p> <p>8 aspirations if they have to be ultrasound guided.</p> <p>9 So, yes, I'm speaking to patients sometimes in</p> <p>10 that situation and, obviously, when I do</p> <p>11 fine-needle aspirations.</p> <p>12 Q. Okay. But you don't have a group of</p> <p>13 patients that come to you for ongoing care and</p> <p>14 see you in an office setting, do you?</p> <p>15 A. They are basically -- I would say it's</p> <p>16 the equivalent of physician referral. So if a --</p> <p>17 if a clinician is doing a biopsy -- I mentioned</p> <p>18 women with Pap smears and then cervical biopsies</p> <p>19 and then cone LEEPs, you know, it's a trajectory</p> <p>20 of care, but it's physician referred for tissue.</p> <p>21 Q. When you say "physician referred," what</p> <p>22 do you -- what do you mean by that? Are you</p> <p>23 interacting with the physician in providing</p> <p>24 advice or recommendations or are you interacting</p> <p>25 with the patients themselves and providing advice</p>	<p>1 A. That's correct. They're not scheduled</p> <p>2 to see me.</p> <p>3 Q. Okay. And so outside of, like you</p> <p>4 mentioned, procedures like a fine-needle</p> <p>5 aspiration, you wouldn't generally see patients</p> <p>6 directly.</p> <p>7 A. The fine-needle aspiration would be the</p> <p>8 only setting where they would have a scheduled,</p> <p>9 allotted slot time with me.</p> <p>10 Q. Okay. Generally speaking, when you're</p> <p>11 reviewing slides, what sort of medical records do</p> <p>12 you have available to you that are relevant to</p> <p>13 your clinical diagnosis?</p> <p>14 A. I have the entire medical record</p> <p>15 available to me, whatever is in the hospital</p> <p>16 system for that patient.</p> <p>17 Q. What do you routinely rely on or review</p> <p>18 as part of your review of slides in terms of</p> <p>19 medical records?</p> <p>20 A. Well, it's very patient dependent and</p> <p>21 very diagnosis dependent, but, for example --</p> <p>22 I'll stick to the example of cervical biopsy. So</p> <p>23 I'll be looking -- if I have a cervical biopsy,</p> <p>24 I'll look to see the patient's history of Pap</p> <p>25 smears, HPV tests, that kind of thing.</p>
Page 23	Page 25
<p>1 or recommendations?</p> <p>2 A. The physicians usually.</p> <p>3 Q. Okay. So I'm asking about patients.</p> <p>4 A. Yeah.</p> <p>5 Q. On a given day -- like what are -- what</p> <p>6 are the days that you're in the office?</p> <p>7 A. Monday through Friday.</p> <p>8 Q. So are there days that you do</p> <p>9 particular tasks, administrative, and then days</p> <p>10 that you do frozen sections or days that you do</p> <p>11 just general pathology reads?</p> <p>12 A. Rarely, I have an administrative day.</p> <p>13 It would be nice to have more, but, typically, I</p> <p>14 am looking at slides the majority of the day.</p> <p>15 I will be doing frozen sections on some</p> <p>16 days, but we have a very collegial atmosphere, so</p> <p>17 I might do frozen sections with another pathologist.</p> <p>18 Some days I'm on cytology, so I'm doing the</p> <p>19 fine-needle aspirations, which is either me</p> <p>20 performing the fine-needle aspirations or me</p> <p>21 reading a rapid interpretation that an</p> <p>22 interventional radiologist has performed.</p> <p>23 Q. So on -- in a given week, it's not like</p> <p>24 you have a patient clinic where patients come to</p> <p>25 see you and they're scheduled to see you.</p>	<p>1 Q. Documents that are directly relevant to</p> <p>2 your review of the current pathology; is that</p> <p>3 correct?</p> <p>4 A. For the most part, I would say so.</p> <p>5 Q. In other words, you don't go back</p> <p>6 through all of their physician records or</p> <p>7 gynecologic visits, their primary care physician</p> <p>8 records?</p> <p>9 A. Again, it would depend on the</p> <p>10 situation. I mean, if I have a lung tumor case,</p> <p>11 I'll probably be looking at the radiology, the</p> <p>12 radiology reports, the -- I'll pull up a report</p> <p>13 with a primary care physician to look for smoking</p> <p>14 history, that kind of thing, to put the whole</p> <p>15 piece together for the diagnosis.</p> <p>16 Q. Okay. And, Doctor, you're here today</p> <p>17 to provide a deposition as an expert witness on</p> <p>18 behalf of the plaintiffs; is that correct?</p> <p>19 A. Yes.</p> <p>20 Q. And you said you've given one</p> <p>21 deposition in the past?</p> <p>22 A. Yes, that's correct.</p> <p>23 Q. And what sort of case was that?</p> <p>24 A. That was a tobacco case.</p> <p>25 Q. Were you an expert in that case?</p>

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<p>1 A. Yes. It was an individual causation 2 case. 3 Q. Okay. Were you an expert for the 4 plaintiffs or the defendants? 5 A. For the plaintiffs. 6 Q. And what sort of -- what sort of case 7 was that in terms of the injury that was being 8 alleged? 9 A. It was a patient with lung cancer who 10 was suing a tobacco company. 11 Q. And what was your specific -- what was 12 your opinion in that case? 13 A. That it was highly likely that her long 14 history of smoking caused her lung cancer. 15 Q. So -- and I should have gone over this 16 with you in the beginning, but you're familiar 17 with the deposition rules? 18 A. In general, I think. 19 Q. Okay. You're doing a very good job. 20 And the main things to remember is the two of us 21 will try not to speak over each other so that the 22 court reporter can take a clean transcript down. 23 If you need a break at some time, that's 24 fine, just let me know. All I ask is if there's 25 a question pending, you go ahead and finish the</p>	<p>1 MS. AHERN: You're welcome. 2 BY MS. AHERN: 3 Q. Dr. Kane, I've handed you a copy of 4 your Notice of Deposition for today. 5 Have you seen this document before? 6 A. Yes. 7 Q. When did you see it? 8 A. I believe it was sometime in December, 9 because the original deposition date was 10 January 14th. 11 Q. And, Doctor, do you know whether you 12 produced all of the documents that are responsive 13 to the request in Exhibit 1, your deposition 14 notice? 15 MR. ROTMAN: We've objected to a number 16 of them. And so she's producing -- you should go 17 item by item, I think, if you want to -- I'm 18 going to object otherwise. 19 Q. Doctor, do you know what you brought 20 with you today? 21 A. Yes. We have my -- a copy of my 22 updated CV. We have copies of my invoice. I 23 believe I have a copy of -- oh, right. Sorry. 24 I have pages that I found for the Blaustein 25 second edition, which I don't have the actual</p>
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<p>1 answer to the question and then we'll take a 2 break. 3 If you don't understand a question that I 4 ask you, please don't answer it. Let me know 5 that you don't understand the question or you'd 6 like me to rephrase it and I'll be happy to do 7 that. All right? 8 A. Okay. 9 Q. Okay. And if you answer the question, 10 is it fair for me to assume that you understood 11 it? 12 A. Yes. 13 Q. All right. 14 (Notice of Oral and Videotaped 15 Deposition of Sarah E. Kane and Duces Tecum 16 marked Exhibit 1.) 17 BY MS. AHERN: 18 Q. Doctor, I'm handing you what's been 19 marked as Exhibit No. 1 to your deposition. 20 MS. AHERN: I don't know how many 21 people need copies of these. I don't have that 22 many, but -- 23 MR. TISI: I'll take a copy. Thank 24 you. 25 MR. ROTMAN: Thank you.</p>	<p>1 textbook. I believe I got -- I found this image 2 off of the internet. But I do have the fourth 3 and fifth editions of the Kurman Blaustein's 4 textbook, and I've marked any relevant pages that 5 I reviewed a couple of days ago. 6 MS. AHERN: If you -- 7 MR. ROTMAN: One second. 8 MS. AHERN: It might be easier if you 9 just hand me those and let me take a look. 10 MR. ROTMAN: In addition, there's the 11 boxes in the room that are the documents that 12 were sent up by counsel from Ashcraft &amp; Gerel. 13 MS. AHERN: Thank you. 14 BY MS. AHERN: 15 Q. All right, Doctor. So let's take these 16 in order, I guess. Let's look at your -- 17 MR. ROTMAN: She also has a copy of her 18 report. 19 MS. AHERN: Okay. We'll mark your 20 updated CV as Exhibit No. 2. 21 (Curriculum vitae of Sarah E. 22 Kane, M.D. marked Exhibit 2.) 23 BY MS. AHERN: 24 Q. Do you need a copy in front of you? 25 A. Sure.</p>

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<p>1 Q. Okay.</p> <p>2 MS. AHERN: I don't know if anyone else</p> <p>3 needs a copy.</p> <p>4 BY MS. AHERN:</p> <p>5 Q. Doctor, Exhibit 2, this is a copy of</p> <p>6 your current curriculum vitae?</p> <p>7 A. Yes. January 2019, yes, this is the</p> <p>8 current.</p> <p>9 Q. And can you tell me what has been</p> <p>10 updated since you submitted your report</p> <p>11 November 15th of 2018?</p> <p>12 A. I believe the only change is that I am</p> <p>13 now director of cytopathology at North Shore</p> <p>14 Medical Center, which includes Salem Hospital and</p> <p>15 Union Hospital, which is in Lynn, Massachusetts.</p> <p>16 Q. Are there any additional publications</p> <p>17 that you have included on your updated resume --</p> <p>18 or, sorry, updated CV?</p> <p>19 A. I don't believe so.</p> <p>20 Q. The only change is that your position</p> <p>21 has changed to director?</p> <p>22 A. Yes, of cytopathology.</p> <p>23 Q. Okay. And you've also brought with you</p> <p>24 invoices --</p> <p>25 A. Yes.</p>	<p>1 June 16th, which is the last date. So it would</p> <p>2 have been after June 16th, 2017.</p> <p>3 Q. I'm sorry. Do you remember when you</p> <p>4 were retained by the plaintiffs to be an expert</p> <p>5 in this litigation?</p> <p>6 A. I believe I was contacted by Mr. Rotman</p> <p>7 in early May of 2017.</p> <p>8 Q. Okay. Do you know how Mr. Rotman found</p> <p>9 your name?</p> <p>10 A. I believe he was referred by a</p> <p>11 colleague.</p> <p>12 Q. Do you remember what colleague that is?</p> <p>13 A. Dr. Paul Michaels.</p> <p>14 Q. And is Dr. Michaels a pathologist?</p> <p>15 A. Yes.</p> <p>16 Q. Where does Dr. Michaels work?</p> <p>17 A. I actually don't know the name of his</p> <p>18 group, but he is in Austin, Texas now.</p> <p>19 Q. Where was he in 2017?</p> <p>20 A. Austin, Texas, I believe.</p> <p>21 Q. Okay. Is he a gynecologic pathologist?</p> <p>22 A. No.</p> <p>23 Q. What type of pathologist is he?</p> <p>24 A. He has a cytopathology fellowship, in</p> <p>25 addition to anatomic and clinical board</p>
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<p>1 Q. -- for your time spent on talc?</p> <p>2 A. I handed them to her. Yes.</p> <p>3 MR. ROTMAN: What we handed, I think,</p> <p>4 is multiple copies, so you can hand one back, I</p> <p>5 suppose.</p> <p>6 MS. AHERN: We'll mark as Exhibit 3 to</p> <p>7 your deposition an invoice for rendered services.</p> <p>8 (Invoice from Sarah Kane, M.D.,</p> <p>9 for services 5/19 through 7/14 marked</p> <p>10 Exhibit 3.)</p> <p>11 MS. AHERN: I can't see a date, but it</p> <p>12 looks like it covers -- well, let's just have you</p> <p>13 look at it.</p> <p>14 BY MS. AHERN:</p> <p>15 Q. Can you tell me the date range covered</p> <p>16 by that invoice?</p> <p>17 MR. ROTMAN: Copy for me?</p> <p>18 A. Yes. It looks like it is from May 19th</p> <p>19 to June 16th. That would be -- if this is the</p> <p>20 first invoice, I believe, that would be of 2017,</p> <p>21 year 2017.</p> <p>22 Q. Okay. And, Doctor, was this May 19,</p> <p>23 2017 -- how long after you were retained did you</p> <p>24 submit this invoice?</p> <p>25 A. I wouldn't have sent it until after</p>	<p>1 certification.</p> <p>2 Q. And how do you know Dr. Michaels?</p> <p>3 A. We were residents and fellows together.</p> <p>4 Q. Were you -- fellows where? Mass</p> <p>5 General?</p> <p>6 A. At Massachusetts General, yes.</p> <p>7 Q. Was he in the gynecologic pathology</p> <p>8 fellowship with you or a different fellowship?</p> <p>9 A. So my fellowship was kind of</p> <p>10 interesting. I was, unfortunately, one of the</p> <p>11 last groups where a combined anatomic and</p> <p>12 clinical pathology residency was five years. I</p> <p>13 think the next year after I began residency they</p> <p>14 dropped it to four years.</p> <p>15 So my surgical pathology and cytopathology,</p> <p>16 it was a two-year fellowship. The gyn path and</p> <p>17 the cytopathology, it was over a two-year period.</p> <p>18 And the weeks of gynecologic pathology were mixed</p> <p>19 with weeks of cytopathology, so they spread out</p> <p>20 the cytopathology fellowship over two years.</p> <p>21 Paul was a cytopathology fellow the first</p> <p>22 year of my fellowship, so we did all four years</p> <p>23 of anatomic and clinical pathology and then the</p> <p>24 first year of fellowship at the same time.</p> <p>25 Q. Okay. And looking back at Exhibit 3,</p>

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<p>1 this invoice from May 19, 2017, to July 14 of 2 2017, the first entry looks like it's -- it 3 covers a period of May 19th through July 14th, 4 "Communication with firm regarding talc 5 litigation case, one hour"; is that correct? 6 A. Yes. Sorry. Thank you for correcting 7 me. I saw the last line, 6/16, and figured that 8 was the last day that this covered. But you're 9 correct, it's -- July 14th would have been the 10 last date that this invoice covered. 11 Yes, June 16th I met with Mr. Rotman, 12 Dr. Thompson, and Mr. Soileau -- I don't know how 13 to pronounce his last name. 14 Q. Are they all -- they're all attorneys; 15 correct? 16 A. Correct. 17 Q. Okay. What firm? 18 A. I know Mr. Rotman is with Hausfeld. 19 Dr. Thompson is with Allen Beasley. I don't know 20 for sure where Mr. Soileau is from. 21 Q. You said Mr. Thompson is with Beasley 22 Allen. 23 A. I believe so. I don't remember for 24 certain. 25 Q. And at least during --</p>	<p>1 So those hours overlap a little bit. I 2 mean, I kept track of particular hours so that I 3 could bill accurately, but those two things -- 4 certainly, generating the medical expert report 5 would also include review of medical literature. 6 Q. Okay. So you started on your -- on the 7 draft of your expert report in this case back in 8 May of 2017; is that correct? 9 A. Late May, yes. 10 Q. And did you -- do you remember when you 11 started your review of the medical literature? 12 Would it have been May 20th, as reflected in this 13 invoice, Exhibit 3? 14 A. Yes, I believe so. 15 Q. You also have on here that you spent 16 some time researching electron microscopy 17 experts. 18 A. Yes. 19 Q. Was that at the request of the 20 plaintiffs' counsel? 21 A. Plaintiffs' counsel was looking for 22 additional people because there are very few 23 electron microscopy units in the country and very 24 few expert electron microscopists. 25 I can't remember if they asked me to or I</p>
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<p>1 MR. ROTMAN: It's Ms. Thompson. 2 MS. AHERN: Ms. Thompson. 3 MR. ROTMAN: Or Dr. Thompson. 4 THE WITNESS: Doctor. She's a -- she's 5 a doctor, as well as an attorney. 6 Q. And for this first invoice, you billed 7 \$26,666.67; correct? 8 A. Yes. 9 Q. And you spent a total of 53 hours and 10 20 minutes working on talc-related issues? 11 A. Yes. 12 Q. Seventeen hours and five minutes of 13 that was reviewing the medical literature, expert 14 reports, and testimony; is that correct? 15 A. So this was my first time ever 16 recording any sort of invoice for medical expert 17 witness work, so the review of medical 18 literature, expert reports, and testimony, 19 probably some of that will also be included in 20 the generating of medical expert report, because 21 while I was -- I basically began -- you can see 22 from the dates I pretty much started drafting, 23 taking notes in a draft, around May 28th, which 24 was soon after I did my initial medical 25 literature searches.</p>	<p>1 offered to. It could have been the latter. But 2 I was aware that they were looking for additional 3 people to potentially use electron microscopy. 4 Q. Do you know how plaintiffs intended to 5 use the electron microscopy experts? 6 MR. ROTMAN: Objection. That's going 7 into areas that you're not entitled to, so she's 8 not going to answer that. 9 BY MS. AHERN: 10 Q. Doctor, what sort of electron 11 microscopists were you looking for at the 12 plaintiffs' request? 13 MR. ROTMAN: Same objection. 14 MS. AHERN: I'm not asking her about 15 communications that she had with counsel; I'm 16 asking her what sort of work -- 17 MR. ROTMAN: Your question -- 18 MS. AHERN: -- she did -- 19 MR. ROTMAN: Your question -- 20 MS. AHERN: -- that she was paid for by 21 the plaintiffs' counsel and that's reflected on 22 the invoice that you've submitted here today. 23 MR. ROTMAN: You are asking her what 24 she was doing at plaintiffs' counsel's request. 25 That's unrelated to her --</p>

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<p>1 MS. AHERN: You're --</p> <p>2 MR. ROTMAN: -- opinions.</p> <p>3 MS. AHERN: -- instructing her not to</p> <p>4 answer the question of, "Doctor, what sort of</p> <p>5 electron microscopists were you looking for at</p> <p>6 plaintiffs' request?"</p> <p>7 MR. ROTMAN: Yes. I'm objecting to</p> <p>8 that.</p> <p>9 MR. KLATT: That's not a communication.</p> <p>10 MS. AHERN: That's not a communication.</p> <p>11 That is what did she do and what was she looking</p> <p>12 for.</p> <p>13 MR. TISI: It's consulting.</p> <p>14 MS. AHERN: She's sitting here today as</p> <p>15 a testifying expert.</p> <p>16 MR. ROTMAN: Understood. She's not</p> <p>17 going to answer that.</p> <p>18 BY MS. AHERN:</p> <p>19 Q. Doctor, did you make any</p> <p>20 recommendations regarding electron microscopists?</p> <p>21 A. No, ultimately, I did not give them any</p> <p>22 names.</p> <p>23 Q. What electron microscopists were you</p> <p>24 looking at when you were conducting your</p> <p>25 research?</p>	<p>1 P-E-T-U-R.</p> <p>2 Q. N-I-E-, Nielsen?</p> <p>3 A. I believe so.</p> <p>4 Q. -S-S-O-N?</p> <p>5 A. No, -L-S-E-N.</p> <p>6 Q. Did you speak to Dr. Nielsen about</p> <p>7 potentially working on the talc litigation?</p> <p>8 A. I believe I e-mailed him.</p> <p>9 Q. Do you remember when that occurred?</p> <p>10 A. It was probably -- I don't remember</p> <p>11 exactly, but I would imagine it was between 5/22</p> <p>12 and 6/1 of 2017.</p> <p>13 Q. And was he interested in doing any talc</p> <p>14 work?</p> <p>15 A. He was not interested in doing medical</p> <p>16 expert witness or consulting work.</p> <p>17 Q. Did you e-mail anybody else, any other</p> <p>18 electron microscopists?</p> <p>19 MR. ROTMAN: So you keep on asking her</p> <p>20 about the consulting work that she was doing that</p> <p>21 had nothing to do with her opinions in this case,</p> <p>22 which is why we're here today. We're not here</p> <p>23 today for you to take the deposition of her</p> <p>24 consulting work at that stage on this issue, so</p> <p>25 that whole area is off limits and I'm instructing</p>
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<p>1 MR. ROTMAN: Again, this is her work</p> <p>2 on -- as a consultant not relating to her</p> <p>3 opinions in this case --</p> <p>4 Q. Doctor, do you --</p> <p>5 MR. ROTMAN: -- so you're not entitled</p> <p>6 to this information.</p> <p>7 MS. AHERN: You're instructing her not</p> <p>8 to answer.</p> <p>9 MR. ROTMAN: Yes.</p> <p>10 MS. AHERN: Then instruct her not to</p> <p>11 answer.</p> <p>12 MR. ROTMAN: I'm instructing you not to</p> <p>13 answer.</p> <p>14 THE WITNESS: Okay.</p> <p>15 BY MS. AHERN:</p> <p>16 Q. Doctor, do you know any electron</p> <p>17 microscopists?</p> <p>18 A. Yes.</p> <p>19 Q. Who?</p> <p>20 A. I know Dr. Gunnlaugur Nielsen at</p> <p>21 Massachusetts General Hospital.</p> <p>22 Q. How do you spell Gunnlaugur's name?</p> <p>23 A. G-U-N-N -- I believe there are two</p> <p>24 Ns -- L-A-U-G-H-E-R [sic], Nielsen. That's with</p> <p>25 an S-E-N. But he goes by Petur, which is</p>	<p>1 her not to answer. If you want to continue</p> <p>2 asking those questions, I'm going to continue to</p> <p>3 object on the same basis.</p> <p>4 Q. Doctor, did you contact any electron</p> <p>5 microscopists who agreed to work on the talc</p> <p>6 litigation?</p> <p>7 MR. ROTMAN: Objection.</p> <p>8 Instruct you not to answer for the</p> <p>9 reasons previously provided.</p> <p>10 Q. Doctor, do you know a Dr. Campion?</p> <p>11 A. I do not.</p> <p>12 Q. Do you know a Dr. John Godleski?</p> <p>13 A. I know the name. I do not know him</p> <p>14 personally.</p> <p>15 Q. Do you know Bill Welch?</p> <p>16 A. I know the name. I do not know him</p> <p>17 personally.</p> <p>18 Q. Okay.</p> <p>19 (Invoice from Sarah Kane, M.D.,</p> <p>20 for services 7/28 through 9/12 marked</p> <p>21 Exhibit 4.)</p> <p>22 BY MS. AHERN:</p> <p>23 Q. Doctor, I'm handing you what's been</p> <p>24 marked as Exhibit 4 to your deposition.</p> <p>25 Can you tell me what that is?</p>

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<p>1 A. This is probably the second invoice. 2 Again, I don't believe I had it numbered on the 3 actual invoice, but this looks like it would be 4 the second invoice. 5 Q. And what period of time does Exhibit 4 6 cover? 7 A. This covers July 28th to September 12. 8 Q. Is this 2017? 9 A. Yes. 10 Q. And you spent an additional 37 hours 11 and 40 minutes reviewing literature and 12 generating your expert report; is that correct? 13 A. Right. And you'll see I actually 14 combined everything, because it got too 15 complicated to separate them out. And generating 16 the medical expert report was sort of this 17 organic part of reviewing the literature. 18 Q. And the total bill was for \$19,666.67; 19 correct? 20 A. Yes. 21 Q. Okay. Was all your time on Exhibit 4 22 spent working on your MDL report? 23 A. I'm sorry. This invoice? 24 Q. Yes, ma'am. Was the time spent on 25 Exhibits 3 and 4, these first two invoices, was</p>	<p>1 Q. Who's been your primary contact? 2 A. Mr. Rotman. 3 Q. Okay. And a total for that bill was 4 \$13,835; is that correct? 5 A. Yes. 6 (Invoice from Sarah Kane, M.D., 7 for services 2/23/18 through 8/3/18 marked 8 Exhibit 6.) 9 BY MS. AHERN: 10 Q. I'm handing you what's been marked as 11 Exhibit 6 to your deposition. 12 Can you tell me what that document is, 13 please? 14 A. So this -- I'm counting now -- looks 15 like this is the fourth invoice -- yes, the 16 fourth invoice that I sent them. 17 Q. And what period of time does this 18 Exhibit 6 cover? 19 A. It looks like February 23rd, 2018, 20 through August 7th, 2018. 21 Q. Okay. And Exhibit 6 reflects that you 22 spent an additional 16 hours and 55 minutes 23 reviewing literature and generating your medical 24 expert report; is that correct? 25 A. Yes.</p>
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<p>1 this all in relation to your work on the talc 2 MDL? 3 A. Yes. I'm not involved in any other 4 talc litigation. 5 Q. Okay. 6 MS. AHERN: Okay. I'm marking 7 Exhibit 5 as -- oh, I'm marking, sorry, your 8 third invoice as Exhibit 5 to your deposition. 9 (Invoice from Sarah Kane, M.D., 10 for services 9/18/17 through 2/5/18 marked 11 Exhibit 5.) 12 BY MS. AHERN: 13 Q. This is a copy of an invoice submitted 14 by you; correct? 15 A. Yes. 16 Q. And what dates does it cover? 17 A. This covers September 18th, 2017, to 18 February 5th, 2018. 19 Q. You spent an additional 27 hours and 40 20 minutes working on your report; is that correct? 21 A. Yes. Well, 21 hours, 55 minutes 22 reviewing the literature and the medical expert 23 witness report, and then there were a few hours 24 communicating and meeting with the firm, which 25 would likely be Mr. Rotman.</p>	<p>1 Q. And 3 hours and 30 minutes 2 communicating or meeting with the law firms 3 involved. 4 A. Correct. 5 Q. Okay. And the total for that invoice 6 was \$10,208; correct? 7 A. Correct. 8 Q. Okay. I'm handing you what's been 9 marked as Exhibit 7 to your deposition. 10 (Invoice from Sarah Kane, M.D., 11 for services 9/20/18 through 11/16/18 12 marked Exhibit 7.) 13 BY MS. AHERN: 14 Q. And this is another invoice prepared by 15 you? 16 A. Yes. 17 Q. And the period of time that is covered 18 appears to be September 20th, 2018, through 19 November 16th of 2018; is that right? 20 A. Yes. 21 Q. And you spent an additional 71 hours 22 and 5 minutes reviewing materials and generating 23 your expert report? 24 A. Yes. 25 Q. And about four-and-a-half hours</p>

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<p>1 communicating with the law firms involved?</p> <p>2 A. That's correct.</p> <p>3 Q. For a total of \$37,791.67?</p> <p>4 A. Yes.</p> <p>5 Q. Doctor, do you have any -- this takes</p> <p>6 us through -- this last invoice, Exhibit 7, takes</p> <p>7 us through November of 2018.</p> <p>8 You've done additional work since November</p> <p>9 of 2018; correct?</p> <p>10 A. I have.</p> <p>11 Q. Do you know how much time you have yet</p> <p>12 to invoice or -- sorry, let me back up. Withdraw</p> <p>13 that.</p> <p>14 Have you sent another invoice to plaintiffs'</p> <p>15 counsel?</p> <p>16 A. I have not.</p> <p>17 Q. Okay. Do you have any idea how many</p> <p>18 hours you have yet to invoice?</p> <p>19 A. I have not added it up. I don't really</p> <p>20 have a ballpark. Maybe -- I would just be</p> <p>21 guessing. I haven't added it up, to be honest.</p> <p>22 Q. Do you know how much money you've made</p> <p>23 to date, totaling all of these together?</p> <p>24 MR. ROTMAN: Objection.</p> <p>25 Q. How much money -- how much money have</p>	<p>1 and produce it to one of the attorneys involved?</p> <p>2 A. Sure.</p> <p>3 Q. Thank you.</p> <p>4 MR. ROTMAN: She'll find it if it</p> <p>5 exists. She'll look for it.</p> <p>6 MS. AHERN: Clearly.</p> <p>7 MR. ROTMAN: She didn't testify that</p> <p>8 she produced a fee schedule; she said she</p> <p>9 believed she did.</p> <p>10 MS. AHERN: Understood. If she finds</p> <p>11 it --</p> <p>12 MR. ROTMAN: Yeah.</p> <p>13 MS. AHERN: -- she'll produce it to you</p> <p>14 and you'll produce it to us.</p> <p>15 MR. ROTMAN: Exactly.</p> <p>16 BY MS. AHERN:</p> <p>17 Q. Doctor, how much -- I mean, how do you</p> <p>18 keep track of your time? Do you have a</p> <p>19 spreadsheet? Do you have some process where you</p> <p>20 log your hours?</p> <p>21 A. I keep a list, an electronic list.</p> <p>22 It's not an Excel, but it's just a list.</p> <p>23 Q. So is it just a Word document and you</p> <p>24 put your time entries in and multiply that by</p> <p>25 your hourly rate?</p>
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<p>1 you made in fees associated with your talc work</p> <p>2 to date?</p> <p>3 A. I would need a calculator to add it all</p> <p>4 up, but this would be the full amount, all added</p> <p>5 together.</p> <p>6 Q. And, Doctor, you're charging \$500 an</p> <p>7 hour; correct?</p> <p>8 A. Yes.</p> <p>9 Q. Did you ask for a retainer when you</p> <p>10 were initially asked to get involved in the case?</p> <p>11 A. I did not.</p> <p>12 Q. Were you offered a retainer?</p> <p>13 A. It wasn't discussed.</p> <p>14 Q. Does the amount that you charge or your</p> <p>15 fee, does that change with the activity that</p> <p>16 you're performing?</p> <p>17 A. No. I think I had a fee schedule where</p> <p>18 trial might be on a per-day basis, but I don't</p> <p>19 remember what that is.</p> <p>20 Q. Did you actually submit a written fee</p> <p>21 schedule to the plaintiffs' counsel?</p> <p>22 A. I believe I did at some point.</p> <p>23 MR. ROTMAN: I don't know. I don't</p> <p>24 recall that.</p> <p>25 Q. Could you find a copy of that, please,</p>	<p>1 A. Basically.</p> <p>2 Q. And do you generate the invoices</p> <p>3 yourself?</p> <p>4 A. I do.</p> <p>5 Q. Is that through some sort of program or</p> <p>6 is this just a Word document that you created and</p> <p>7 you plug the information in?</p> <p>8 A. It's just a Word document.</p> <p>9 (Discussion off the record.)</p> <p>10 BY MS. AHERN:</p> <p>11 Q. So, Doctor, other than the folders that</p> <p>12 we've just gone through, is there anything</p> <p>13 related to your opinions in this case that you</p> <p>14 did not bring with you to the deposition today?</p> <p>15 MR. ROTMAN: Objection.</p> <p>16 Q. Start with that.</p> <p>17 MR. ROTMAN: Objection.</p> <p>18 A. I believe I brought all of the</p> <p>19 literature cited in the initial reports. I've</p> <p>20 tried to be complete, as you know, with listing</p> <p>21 everything that I've reviewed. It's possible</p> <p>22 there might have been some things that I reviewed</p> <p>23 that I forgot to put on a list, but I've tried to</p> <p>24 be as complete as possible.</p> <p>25 Q. How did you track your literature</p>

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<p style="text-align: right;">Page 50</p> <p>1 reviews?</p> <p>2 A. So when I was writing the report,</p> <p>3 you'll notice the first reference list is a list</p> <p>4 of papers that I actually cited in the text of</p> <p>5 the report, and then I had -- any papers that I</p> <p>6 reviewed or other data that I reviewed, I kept in</p> <p>7 folders on my computer.</p> <p>8 Unfortunately, I had two hard drives</p> <p>9 malfunction while I was in the process of writing</p> <p>10 this report. Luckily, I backed up most of it, so</p> <p>11 it's possible a few things didn't get documented,</p> <p>12 ultimately, but I really tried my best to make it</p> <p>13 complete and accurate, and that's why you got</p> <p>14 another list yesterday.</p> <p>15 Q. Okay. And, I'm sorry, we forgot to</p> <p>16 mark some of these.</p> <p>17 And so can you tell me -- this is something</p> <p>18 you brought with you today?</p> <p>19 A. Yes.</p> <p>20 MR. TISI: Can I -- and he's defending</p> <p>21 the deposition; I just have a little more</p> <p>22 knowledge of the documents and how they -- at</p> <p>23 least I think I do.</p> <p>24 I think that in the boxes here are the</p> <p>25 references cited. The materials considered, I</p>	<p style="text-align: right;">Page 52</p> <p>1 MR. KLATT: Chris, let me just clarify.</p> <p>2 There's four blue cardboard TLS boxes --</p> <p>3 MR. TISI: Correct.</p> <p>4 MR. KLATT: -- that you're referring</p> <p>5 to?</p> <p>6 MR. TISI: Correct.</p> <p>7 MR. KLATT: And they have binders in</p> <p>8 them?</p> <p>9 MR. TISI: They have binders in them.</p> <p>10 And I haven't even looked at them because they</p> <p>11 were sent out from the Ashcraft office, but my</p> <p>12 understanding -- and you can crack them open at</p> <p>13 break -- but my understanding is there are copies</p> <p>14 of those. I don't know how many. So it's four</p> <p>15 boxes, but there are duplicates in there.</p> <p>16 But they are -- if I understand -- and</p> <p>17 I can correct them on a break -- if I understand</p> <p>18 them, they are copies of the references. We did</p> <p>19 not make copies -- or they did not make copies of</p> <p>20 the materials that were considered but not</p> <p>21 referenced in the reports.</p> <p>22 Do you follow what I'm saying?</p> <p>23 MR. KLATT: Yeah. What I want to</p> <p>24 clarify is the four boxes here have not been in</p> <p>25 Dr. Kane's possession, so there's no notations,</p>
<p style="text-align: right;">Page 51</p> <p>1 don't think we printed out. I don't think those</p> <p>2 are in the boxes. And so I don't want there to</p> <p>3 be any -- there are documents she reviewed that</p> <p>4 are not here that are not referenced, but were</p> <p>5 identified in that list.</p> <p>6 Does that make sense?</p> <p>7 MS. AHERN: Maybe. I'm going to go</p> <p>8 through the various reference lists with her --</p> <p>9 MR. TISI: Okay.</p> <p>10 MS. AHERN: -- and we can kind of</p> <p>11 clarify as we go.</p> <p>12 MR. TISI: Like, for example, I mean, I</p> <p>13 just -- I'm just using an example -- we</p> <p>14 supplemented with some Health Canada materials.</p> <p>15 I don't know if she brought those with her,</p> <p>16 because they were not in the original report.</p> <p>17 They weren't available at the time, so they would</p> <p>18 not be in the reference materials that are in the</p> <p>19 binders.</p> <p>20 I know you haven't cracked open the</p> <p>21 boxes, but I don't want there to be any</p> <p>22 misimpression. So in terms of what they are, you</p> <p>23 can certainly ask her, but she may not know what</p> <p>24 is in the boxes, because we printed them out for</p> <p>25 her. Do you know what I'm saying?</p>	<p style="text-align: right;">Page 53</p> <p>1 highlighting, stickies --</p> <p>2 MR. TISI: Oh, no.</p> <p>3 MR. KLATT: -- that she -- that</p> <p>4 Dr. Kane herself would have put on what's in the</p> <p>5 boxes --</p> <p>6 MR. TISI: No. Those were print- --</p> <p>7 MR. KLATT: -- is that correct?</p> <p>8 MR. TISI: Correct. Those were printed</p> <p>9 out by the plaintiffs' steering committee.</p> <p>10 Basically, we took her reference list and printed</p> <p>11 them out for you all. There's no -- there are no</p> <p>12 notes from her or anything like that.</p> <p>13 What I don't think we printed out for</p> <p>14 you would be the extensive documents that she</p> <p>15 reviewed, including the supplemental materials</p> <p>16 that were identified, and then put them -- we can</p> <p>17 provide those in a -- you know, on a thumb drive</p> <p>18 if you want to. It's just in these depositions</p> <p>19 we've had so far, half the time the boxes aren't</p> <p>20 even opened, and we didn't want to just create</p> <p>21 paper for the purpose of creating paper. But if</p> <p>22 you want, we can pull those for you and put them</p> <p>23 in a Dropbox or whatever.</p> <p>24 I don't want to waste your time,</p> <p>25 because I do want there to be -- because she</p>

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<p>1 doesn't necessarily know what was printed out for 2 her. 3 MS. AHERN: Understood. So let's -- 4 MR. TISI: I'm sorry if I -- 5 MS. AHERN: That's okay. 6 MR. TISI: -- took up time. 7 (Excerpt from Blaustein's Second 8 marked Exhibit 8.) 9 BY MS. AHERN: 10 Q. Doctor, I'm handing you what's been 11 marked as Exhibit 8 to your deposition. 12 A. Yes. 13 Q. Is this something that you brought with 14 you today in response to the Notice of 15 Deposition? 16 A. It's something I brought because I 17 reviewed it a couple days ago. It probably falls 18 within the deposition. I know you wanted to see 19 everything that I reviewed. 20 Q. So, first of all, tell me what this is. 21 What is Exhibit 8? 22 A. This is a page from Blaustein's second 23 edition of the Pathology of the Female Genital 24 Tract. 25 Q. Do you know what page it is?</p>	<p>1 Q. And, Doctor, the additional materials 2 to -- of Dr. Sarah Kane that were provided to us 3 yesterday, you list "Kurman defense report" from 4 a case by the name of Ristesund. 5 Did you not receive that? 6 A. I asked for -- yeah, I did receive 7 that. 8 Q. You received it? 9 MR. ROTMAN: What she -- what she was 10 saying is she -- 11 MS. AHERN: Wait. I'm asking her the 12 question. 13 Q. Did you receive the report, the Kurman 14 defense report, from a case by the name of 15 Ristesund? 16 A. Yes. I had requested a defense report 17 written by Kurman, if they had anything, and that 18 is what I received. 19 Q. Okay. I thought just a minute ago you 20 said you had not received one because it wasn't 21 available to you. 22 A. I'm talking about the MDL, the curr- -- 23 Q. Ah. 24 A. -- the current defense expert witness 25 reports.</p>
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<p>1 A. Unfortunately, it is cut off. This -- 2 I don't have this textbook. I found this, I 3 think, on Google Books, actually. 4 Q. And so why are you bringing it today 5 again? 6 A. Because I reviewed it. 7 Q. Okay. And why did you review this? 8 A. Well, I recently became aware that 9 Dr. Kurman is a medical expert witness for the 10 defense, so I was more curious. I actually asked 11 the plaintiffs' attorneys for a report -- any 12 report that Dr. Kurman had done, because I was 13 trying to understand his -- what his viewpoint 14 might be. I don't have his defense report 15 because they're not available to us yet, but I 16 was trying to get a sense for what defense 17 medical experts -- their viewpoints. 18 And so I did a search for, basically, "talc" 19 and "Kurman" and I found this (indicating). And 20 then I have two other editions, so I looked 21 through my other editions for any references to 22 talc. Because Kurman edited the fourth and fifth 23 edition. I do not believe he edited the second 24 edition, which is -- this one page is from 25 (indicating).</p>	<p>1 Q. Okay. 2 A. Yeah. 3 Q. Thank you for the clarification. 4 So you have seen at least one defense report 5 that was written by Dr. Bob Kurman; right? 6 A. Yes. 7 Q. And did you -- do you know Dr. Robert 8 Kurman, either personally or by reputation? 9 A. By reputation and I've gone to dinner 10 with him before, but I don't know him well. 11 Q. And what do you know about Dr. Kurman? 12 A. So he is a well-known gynecologic 13 pathologist out of -- he was out of Johns 14 Hopkins. I believe he recently retired. 15 But he certainly edited one of the main 16 gynecologic pathology textbooks and was -- you 17 know, published quite a bit in gynecologic 18 pathology, so his name is well known in our 19 community. 20 Q. And you've actually cited to a number 21 of his papers in your report; correct? 22 A. Yes, I'm sure I have. I know at least 23 one or two. 24 Q. And Dr. Kurman was a Robert Scully 25 fellow, as well, wasn't he?</p>

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<p style="text-align: right;">Page 58</p> <p>1 A. I actually don't remember if he trained 2 under Scully. It's possible. I don't remember 3 whether or not he did. 4 Q. Okay. This Exhibit 8 that you brought 5 with you today, are you bringing it here because 6 it mentions granulomatous endometritis caused by 7 foreign bodies? 8 A. It says, "Talc may be introduced into 9 the endometrial cavity by instruments 10 contaminated with talcum powder or by gloves 11 during a pelvic examination. Patients may be 12 asymptomatic or may present with menorrhagia. 13 Microscopically, the extent of the granulomatous 14 inflammatory reaction depends on the quantity of 15 the talc inoculated. The infiltrate is 16 characterized by histiocytes and foreign-body 17 multinucleated giant cells surrounded -- 18 surrounding the talc crystals, along with 19 lymphocytes and plasma cells. The crystals 20 appear as refractile, birefringent, needle-like, 21 or fan-shaped splinters in polarizing light." 22 Q. Are you familiar with the type of 23 reactions -- tissue reactions that are elicited 24 by talc in tissue? 25 A. I know -- I'm aware that you can get</p>	<p style="text-align: right;">Page 60</p> <p>1 A. I'm not really sure what you mean by 2 "types." You mean foreign body versus infectious 3 versus -- 4 Q. Yes. 5 A. Those would be the top of the list. 6 Q. And are there subtypes of granulomatous 7 inflammation within those categories? 8 A. Well, you can have multinucleated giant 9 cells that aren't part of a granuloma. 10 You can see -- another common situation 11 where you'll see granulomas is in Crohn's 12 disease. That's granulomatous inflammation in 13 the colon due to inflammatory bowel disease. 14 And I think -- yeah. So foreign body and 15 infection are -- and certain diseases that may 16 cause granulomatous -- that's sort of the 17 hallmark of that type of disease, sarcoidosis. 18 Q. Have you ever -- the Figure 12.6 in 19 Exhibit 8 actually doesn't have anything to do 20 with granulomatous endometritis, does it? 21 A. No. That figure is of a type of 22 finding you can see in the endometrium that's not 23 a granulomatous reaction. 24 Q. And how did Exhibit 8, if it does, 25 inform your opinions in this case?</p>
<p style="text-align: right;">Page 59</p> <p>1 granulomous -- granulomatous inflammation, like 2 here, and you can have acute inflammation, for 3 example, in pleurodesis and chronic inflammation, 4 like lymphocytes and plasma cells. 5 Q. Are you an expert in granulomatous 6 inflammation? 7 A. Well, I certainly am familiar with 8 the -- with diagnosis of granulomatous 9 inflammation. I see it quite commonly. 10 Q. Under what circumstances do you 11 commonly see granulomatous inflammation? 12 A. You see it often in -- the most common 13 situation would be foreign-body giant cell. That 14 could be due to foreign bodies or it could be due 15 to -- a common situation we might see them is 16 what's called an epidermal inclusion cyst in the 17 skin, and you actually can get a granulomatous 18 response to keratin that has -- if it's ruptured 19 and gone into the dermis, you can see that. 20 Infections is another one. In tuberculosis, 21 you can see granulomatous inflammation. Fungal 22 infections, you can see granulomatous 23 inflammation. 24 Q. How many different types of 25 granulomatous reactions are there?</p>	<p style="text-align: right;">Page 61</p> <p>1 A. Well, it was just a piece of 2 information I found, again because I was curious 3 mostly about what Kurman's opinion might be on 4 this litigation. So... 5 Q. Does -- do you know what -- did this 6 come from a particular chapter in Blaustein's 7 second edition? 8 A. This, I don't -- I have no more 9 information on this particular one. Um -- 10 Q. Do you know who authored the chapter? 11 MR. ROTMAN: Excuse me. I think she 12 was in the middle of an answer. 13 Q. I didn't mean to cut you off. Please 14 go ahead. 15 A. Again, I don't have any more 16 information. I brought it because I saw it. 17 Q. Okay. So you don't know who authored 18 the chapter that contains this information in 19 Exhibit 8? 20 A. Not for this edition, I do not. 21 Q. And are you -- do you -- did you say 22 earlier you weren't sure if Dr. Kurman edited 23 this particular version of Blaustein's Pathology? 24 A. I don't believe he did. I know he 25 edited the fourth and fifth, but I don't believe</p>

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<p>1 he did the second.</p> <p>2 Q. Does the information in Exhibit 8</p> <p>3 inform your decisions regarding talc and</p> <p>4 causation with regard to ovarian cancer?</p> <p>5 MR. ROTMAN: Objection.</p> <p>6 A. It's another piece of evidence. It</p> <p>7 mentions granulomatous inflammation due to talc</p> <p>8 in the endometrium.</p> <p>9 Q. And what does that have to do with</p> <p>10 ovarian cancer?</p> <p>11 A. Well, one of the plausible biologic</p> <p>12 mechanisms for talc causing ovarian cancer is</p> <p>13 that it elicits a chronic inflammatory reaction.</p> <p>14 Q. And there are different types of</p> <p>15 chronic inflammatory reactions, aren't there?</p> <p>16 A. Yes, there are.</p> <p>17 Q. Is a foreign-body reaction the same as</p> <p>18 the type of inflammation seen, for instance, in</p> <p>19 ulcerative colitis? If you know.</p> <p>20 A. No, I'm just rereading the question.</p> <p>21 Ulcerative colitis, you don't typically see</p> <p>22 foreign-body reaction.</p> <p>23 Q. Ulcerative colitis is one of the</p> <p>24 conditions that has been associated with the</p> <p>25 development of cancer; correct?</p>	<p>1 going to --</p> <p>2 MS. AHERN: One second, please.</p> <p>3 Q. You can see inflammatory conditions</p> <p>4 that are not in any way linked to the development</p> <p>5 of cancer; correct?</p> <p>6 A. So not all chronic inflammation is</p> <p>7 going to lead to cancer, but chronic inflammation</p> <p>8 is a well-established cause of different types of</p> <p>9 cancer.</p> <p>10 MR. ROTMAN: I'd like to take a break.</p> <p>11 We've been going a little over an hour.</p> <p>12 MS. AHERN: Okay.</p> <p>13 THE VIDEOGRAPHER: Here ends Media 1.</p> <p>14 Off the record, 10:21 a.m.</p> <p>15 (A recess was taken.)</p> <p>16 THE VIDEOGRAPHER: Here begins Media</p> <p>17 No. 2 in today's deposition of Sarah Kane, M.D.</p> <p>18 Back on the record, 10:37 a.m.</p> <p>19 BY MS. AHERN:</p> <p>20 Q. All right. Dr. Kane, we were -- we</p> <p>21 left off, we were talking about chronic</p> <p>22 inflammation and cancer.</p> <p>23 Do you remember that?</p> <p>24 A. Yes.</p> <p>25 Q. Okay. Can you identify for me the</p>
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<p>1 A. Those with ulcerative colitis have an</p> <p>2 increased risk of colon cancer, yes.</p> <p>3 Q. Do you know of any particular cancers</p> <p>4 that have been linked to foreign-body responses?</p> <p>5 A. Well, foreign-body responses -- for</p> <p>6 example, asbestos is known to cause an</p> <p>7 inflammatory response and asbestos is known to</p> <p>8 cause mesothelioma and lung cancer, and the IARC</p> <p>9 states that it causes ovarian cancer.</p> <p>10 Q. And how is the response to asbestos</p> <p>11 different from the response that's been</p> <p>12 documented with talc in terms of tissue reaction?</p> <p>13 A. So you can see a granulomatous reaction</p> <p>14 to talc. You can see an acute reaction to talc</p> <p>15 in pleurodesis patients.</p> <p>16 This page here mentions plasma cells and</p> <p>17 lymphocytes, which you do see in Crohn's disease.</p> <p>18 Q. You see plasma cells and lymphocytes in</p> <p>19 a number of different inflammatory conditions;</p> <p>20 correct?</p> <p>21 MR. ROTMAN: You can answer.</p> <p>22 A. Yes, you can see lymphocytes and plasma</p> <p>23 cells in inflammatory conditions.</p> <p>24 Q. And you can see inflammatory con- --</p> <p>25 MR. ROTMAN: Object -- object -- I was</p>	<p>1 types of ovarian cancer that have been associated</p> <p>2 with chronic inflammation?</p> <p>3 A. So we know that endometriosis, as an</p> <p>4 example, causes an inflammatory response. The</p> <p>5 types of ovarian cancer that are associated with</p> <p>6 endometriosis are clear cell carcinoma and</p> <p>7 endometrioid carcinoma.</p> <p>8 Q. Are there other forms of ovarian cancer</p> <p>9 that are associated in the literature with</p> <p>10 chronic inflammation?</p> <p>11 A. So we do see chronic inflammation</p> <p>12 within other types of ovarian cancer, so</p> <p>13 high-grade invasive serous, low-grade serous</p> <p>14 carcinoma, you do see chronic inflammation within</p> <p>15 those tumors.</p> <p>16 Q. Let me be more precise, because it's</p> <p>17 sort of a chicken and the egg kind of thing.</p> <p>18 I'm asking what sort of inflammatory</p> <p>19 conditions have been associated with the</p> <p>20 development or the cause of ovarian cancers?</p> <p>21 A. Yeah. So the mechanisms of a lot of</p> <p>22 ovarian cancer have been somewhat elusive.</p> <p>23 Unfortunately, it's a rare disease. It's hard to</p> <p>24 study. It's difficult to have sort of a large</p> <p>25 enough cohort to really get good data on ovarian</p>

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<p style="text-align: right;">Page 66</p> <p>1 cancer, and so we don't really know all of the 2 mechanisms of the initiation of ovarian cancer. 3 But we know that chronic inflammation, we 4 see it in ovarian tumors. We know that -- and 5 putting it in a talc perspective, we know that 6 talc can cause chronic inflammation and so -- and 7 we know that chronic inflammation causes other 8 types of cancer. 9 Q. So is that -- can you name any other 10 types of ovarian cancers that have been 11 associated in the literature with chronic 12 inflammation in terms of a specific etiology for 13 that cancer? 14 A. So, again, I would say I don't know if 15 we can say for certain what the specific etiology 16 is for all types of surface epithelial cancer, 17 but we do know that, again, clear cell has been 18 associated with endometriosis, which causes 19 chronic inflammation, and we see chronic 20 inflammation in tumors. But the mechanisms for 21 these types of tumors have not been completely 22 mechan- -- elucidated. 23 Q. So do you not know of any other 24 specific ovarian tumors that have been associated 25 in the literature causally with chronic</p>	<p style="text-align: right;">Page 68</p> <p>1 inflammation, yes. 2 Q. And you would agree that many, if not 3 most, cancers are somewhat proinflammatory. 4 A. I think tumors can be -- can be 5 proinflammatory, yes. 6 Q. So the tumor itself can invoke an 7 inflammatory response during its development; 8 correct? 9 A. Some tumors will. 10 Q. And often the tumors will hijack 11 portions of the immune system to help them to 12 grow and metastasize; correct? 13 A. I'm not sure exactly what you mean by 14 "hijack," but there are mechanisms to -- or 15 literature to suggest that. 16 Q. So just looking at a high-grade serous 17 carcinoma and seeing inflammation doesn't tell 18 you anything about whether that inflammation 19 caused the tumor or whether it was caused by the 20 tumor; is that correct? 21 A. So, again, the mechanisms are not that 22 clear, so we don't know for sure. But is all 23 chronic inflammation seen in a tumor the cause of 24 the tumor? I don't know if we know the answer, 25 but, you know, it's definitely an associated</p>
<p style="text-align: right;">Page 67</p> <p>1 inflammation? 2 A. Again, I don't believe that the 3 mechanisms of all of these tumors have been 4 elucidated completely. 5 Q. And I do understand your answer, but I 6 just want to know if there are -- if you're aware 7 of literature connecting causally chronic 8 inflammation with other types of ovarian cancer 9 other than the two that you've mentioned, 10 endometrioid and clear cell carcinoma. 11 A. Well, again, I mentioned that in serous 12 tumors, we do see chronic inflammation in those 13 tumors. 14 And with smoking and mucinous ovarian 15 cancers, you know, it's been -- there's some 16 literature that suggests, you know, smoking is 17 associated with mucinous and those -- that can 18 cause inflammatory reactions. 19 But, again, this is all -- it's not entirely 20 clear what the etiology of some of these tumors 21 are. 22 Q. You mentioned that in high-grade serous 23 carcinoma, you see associated inflammation; 24 correct? 25 A. You can see associated chronic</p>	<p style="text-align: right;">Page 69</p> <p>1 pattern that we see with ovarian tumors. 2 Q. So my question is a little different, 3 if I can go back and find it. And it's missing. 4 My question is: As a pathologist looking at 5 slides from a particular patient who has ovarian 6 cancer -- 7 A. Mm-hmm. 8 Q. -- just the observation that there is 9 inflammatory cells associated with that tumor 10 doesn't tell you anything, as a pathologist, in 11 terms of whether that inflammation caused the 12 tumor or if the tumor caused the inflammation. 13 A. Well, I think it depends on the 14 situation. You know, again, for ovarian tumors, 15 if we have a clear cell carcinoma, we could, you 16 know, deduce, especially if you see associated 17 endometriosis, that that is the likely cause, 18 and, again, depending on the patient and the 19 patient's risk factors. 20 But, yeah, if you're looking just at one 21 slide without any other information, it would be 22 difficult to say. 23 Q. Well, you would never just be looking 24 at one slide, would you? You'd be looking at all 25 of the slides that were available for a</p>

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<p>1 particular patient, which would include</p> <p>2 diagnostic tissue or tumor tissue, as well as</p> <p>3 normal, nontumor tissue; correct?</p> <p>4 A. Right.</p> <p>5 Q. Okay. So you would never be in a</p> <p>6 situation where you're just looking at a single</p> <p>7 slide and making a determination, unless it's</p> <p>8 maybe cytology or a biopsy; correct?</p> <p>9 A. I'm sorry. I'm just looking at the --</p> <p>10 Q. Sure.</p> <p>11 A. I'm not sure what the -- the first</p> <p>12 question came out kind of funny.</p> <p>13 Q. What I was saying is there would never</p> <p>14 be a situation where you're only looking at a</p> <p>15 single slide to make a diagnostic determination</p> <p>16 unless it was from a biopsy sample or a cytology.</p> <p>17 A. That's what I was going to kind of</p> <p>18 rewind and clarify, that sometimes there is only</p> <p>19 one slide. So --</p> <p>20 Q. Is that an accurate statement?</p> <p>21 MR. ROTMAN: Let her finish the answer.</p> <p>22 I think she was saying "so" and then you asked</p> <p>23 another question.</p> <p>24 A. So in a larger specimen type, it's</p> <p>25 correct you would be looking, usually, at more</p>	<p>1 MS. AHERN: I'm not finished with my</p> <p>2 question. You can object when I'm done with my</p> <p>3 question.</p> <p>4 MR. ROTMAN: I object to you asking a</p> <p>5 question --</p> <p>6 MR. KLATT: She didn't have --</p> <p>7 MR. ROTMAN: -- when she's asking --</p> <p>8 MS. AHERN: I can ask a question</p> <p>9 whenever I want. She doesn't have to answer the</p> <p>10 question if you instruct her not to, but while</p> <p>11 she's spending time looking through her report,</p> <p>12 I'm going to ask her a different question based</p> <p>13 on her recollection.</p> <p>14 MR. ROTMAN: Well, you've asked her a</p> <p>15 question, she's in the process of answering it,</p> <p>16 and you're asking -- you're asking her a second</p> <p>17 question. That's what I'm objecting to.</p> <p>18 BY MS. AHERN:</p> <p>19 Q. Doctor --</p> <p>20 MR. ROTMAN: Let her finish --</p> <p>21 Q. -- can you answer the question without</p> <p>22 looking at your report?</p> <p>23 A. Well, I'd like to refer to my report if</p> <p>24 you're asking questions.</p> <p>25 Q. And that's fine. My only question,</p>
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<p>1 slide if there's more tissue that would fit in</p> <p>2 one cassette to make one slide.</p> <p>3 Q. Let's talk about high-grade serous</p> <p>4 carcinoma.</p> <p>5 High-grade serous carcinoma is the most</p> <p>6 common form of ovarian cancer; correct?</p> <p>7 A. It's most -- yes.</p> <p>8 Q. By far the most common form of ovarian</p> <p>9 cancer; is that also correct?</p> <p>10 A. It's the most common form, yes.</p> <p>11 Q. So let's talk about high-grade serous</p> <p>12 carcinoma in the context of chronic inflammation.</p> <p>13 Do you know of any published literature that</p> <p>14 connects chronic inflammation causally with the</p> <p>15 development of high-grade serous carcinoma?</p> <p>16 A. I can -- in my report, I actually do</p> <p>17 have a section. Let me find it.</p> <p>18 MR. ROTMAN: It might be easier to take</p> <p>19 off the clip, if that helps you flip the pages,</p> <p>20 because it's two-sided.</p> <p>21 Q. Doctor, while you look for that, just</p> <p>22 to the best of your recollection, do you remember</p> <p>23 reading any studies that concluded that --</p> <p>24 MR. ROTMAN: I object. She's in the</p> <p>25 middle of answering --</p>	<p>1 really, was, just based on your recollection as</p> <p>2 we sit here discussing chronic inflammation and</p> <p>3 ovarian cancer, if you are aware of studies that</p> <p>4 causally associate chronic inflammation with</p> <p>5 high-grade serous carcinoma?</p> <p>6 A. So there's definitely literature that</p> <p>7 has looked at associations between chronic</p> <p>8 inflammation and the resulting sort of</p> <p>9 expressions.</p> <p>10 And that's what -- I was trying to point you</p> <p>11 to my report on Page 12, the end of it, where it</p> <p>12 says, "There also is evidence that talc induces</p> <p>13 macrophage TNF alpha expression and macrophages</p> <p>14 that express TNF alpha promote ovarian tumor</p> <p>15 genesis. TNF alpha is involved in chronic</p> <p>16 inflammation and induces mutations in vitro and</p> <p>17 TNF alpha-induced chromosomal mutations occur</p> <p>18 mostly in cells with P53 aberrations and, of</p> <p>19 note, high-grade serous carcinomas typically have</p> <p>20 inactivating mutations in P53."</p> <p>21 So, again, we don't know all the mechanisms</p> <p>22 of all of these tumors, but there's certainly</p> <p>23 literature that is investigating those types of</p> <p>24 associations.</p> <p>25 MR. KLATT: Object. Nonresponsive.</p>

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<p>1 MS. AHERN: Same.</p> <p>2 Q. But since you brought it up, on Page 12</p> <p>3 of your report, can you translate for me that</p> <p>4 paragraph that you just read and put it in lay</p> <p>5 terms and explain how that has anything to do</p> <p>6 with causal associations with ovarian cancer and</p> <p>7 chronic inflammation caused by talc?</p> <p>8 MR. ROTMAN: Objection.</p> <p>9 A. Well, I think it's there in the report.</p> <p>10 If talc is inducing macrophage TNF alpha</p> <p>11 expression and macrophages that express TNF alpha</p> <p>12 can promote ovarian tumor genesis that occur</p> <p>13 mostly in the -- TNF alpha-induced chromosomal</p> <p>14 mutations occur mostly in cells with P53</p> <p>15 aberrations, I think that's relevant in looking</p> <p>16 at evidence that -- for a plausible mechanism</p> <p>17 that inflammation caused by talc can cause</p> <p>18 aberrations in -- can cause P53 aberrations. And</p> <p>19 we know that high-grade serous carcinomas, many</p> <p>20 of them have P53 mutations.</p> <p>21 Q. And high-grade serous carcinomas with</p> <p>22 P53 mutations, what causes the P53 mutations?</p> <p>23 A. Well, again, the literature is still</p> <p>24 evolving into all of the mechanisms regarding</p> <p>25 this. Some of them we know are sort of aberrant</p>	<p>1 genomic event in the development of high-grade</p> <p>2 serous carcinoma?</p> <p>3 A. So, again, I don't know if I -- I don't</p> <p>4 know if we always know what the earliest</p> <p>5 identifiable genomic event in the development of</p> <p>6 high-grade serous carcinoma is.</p> <p>7 Q. Have you reviewed the literature on</p> <p>8 high-grade serous carcinoma from a molecular</p> <p>9 genetics perspective?</p> <p>10 A. Yes, I reviewed papers on molecular</p> <p>11 genetics, yes.</p> <p>12 Q. Do those papers indicate that one of</p> <p>13 the earliest, if not the earliest, genomic event</p> <p>14 in the development of high-grade serous carcinoma</p> <p>15 that has been identified are mutations in P53?</p> <p>16 A. So, again, you can see P53 mutations,</p> <p>17 for example, in the fallopian tubes and you can</p> <p>18 have sort of serous tubal intraepithelial</p> <p>19 carcinomas in the fallopian tube, which are</p> <p>20 thought to be early precursors for high-grade</p> <p>21 carcinoma.</p> <p>22 Q. High-grade serous carcinoma?</p> <p>23 A. Mm-hmm. Sorry, high-grade serous</p> <p>24 carcinoma.</p> <p>25 Q. And do you agree that the STIC lesions</p>
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<p>1 mutations, and we don't always know why they</p> <p>2 occur.</p> <p>3 We know that women with BRCA1 and BRCA2</p> <p>4 mutations have -- can get high-grade -- have a</p> <p>5 higher risk of high-grade serous carcinoma.</p> <p>6 But, again, I don't think we know all of the</p> <p>7 mechanisms that cause, you know, all of these</p> <p>8 tumors.</p> <p>9 MS. AHERN: Objection. Nonresponsive.</p> <p>10 Q. Doctor, do you know, as we sit here</p> <p>11 today, what causes P53 mutations in high-grade</p> <p>12 serous carcinoma?</p> <p>13 A. I think I answered that. We know, I</p> <p>14 mean, what's in my report and women with BRCA1</p> <p>15 and BRCA2 mutations. But, again, the literature</p> <p>16 is evolving with this.</p> <p>17 Q. Doctor, are you suggesting that BRCA1</p> <p>18 and -2 mutations cause P53 mutations in</p> <p>19 high-grade serous carcinomas?</p> <p>20 A. What I'm saying is that we know that</p> <p>21 BRCA1 and BRCA2 mutation patients have a high</p> <p>22 risk of ovarian cancer.</p> <p>23 And so you're asking me what causes, so, you</p> <p>24 know, I'm telling you the data that we have.</p> <p>25 Q. What is the earliest identifiable</p>	<p>1 or serous tubal epithelial carcinomas in the</p> <p>2 fallopian tubes are currently known to be the</p> <p>3 earliest manifestation of high-grade serous</p> <p>4 carcinoma?</p> <p>5 A. Well, it depends on what you mean by</p> <p>6 "manifestation." I mean, it takes a period of</p> <p>7 time from initial insult until we can recognize</p> <p>8 something histologically as a precursor to</p> <p>9 cancer.</p> <p>10 Q. That was -- you're right, that was a</p> <p>11 bad question.</p> <p>12 Do you recognize serous tubal</p> <p>13 intraepithelial carcinomas as an in situ serous</p> <p>14 carcinoma?</p> <p>15 A. I think evidence is supportive of</p> <p>16 serous tubal intraepithelial carcinomas being a</p> <p>17 precursor to some high-grade serous carcinomas.</p> <p>18 Q. And when you say "precursor," do you</p> <p>19 mean a frank cancer or a premalignant lesion?</p> <p>20 What do you mean by "precursor"?</p> <p>21 A. Well, again, not -- we don't know if</p> <p>22 all STICs are going to become high-grade serous</p> <p>23 carcinomas. STICs were originally discovered in</p> <p>24 looking at fallopian tubes of BRCA1 and BRCA2</p> <p>25 patients that had -- what's the word I'm looking</p>

20 (Pages 74 to 77)

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<p>1 for? -- prophylactic salpingectomies to decrease 2 their risk of ovarian cancer.</p> <p>3 And that was -- you know, they had evaluated 4 these precursor lesions, and so the thought is 5 that when you have these atypical cells in the 6 fallopian tube fimbria that are -- that have P53 7 aberrations, that that -- the belief is that 8 that's a precursor to some of the serous invasive 9 carcinomas that we see.</p> <p>10 Q. Do you consider STIC lesions to be 11 carcinomas?</p> <p>12 A. They're -- the name is intraepithelial 13 carcinoma, so its analogous term would be sort of 14 an in situ cancer.</p> <p>15 Q. It is a cancer; correct?</p> <p>16 A. Well, they're calling them 17 intraepithelial carcinomas because they have -- I 18 mean, it's sort of semantics. They have a P53 19 mutation and they're recognizable histologically.</p> <p>20 Q. Do you agree that they're carcinomas or 21 cancer?</p> <p>22 A. I certainly agree that they can be 23 precursors to invasive serous carcinomas. It's 24 sort of semantics, precursor -- it -- it's -- 25 it's sort of the same question as ductal</p>	<p>1 that ovulation event, you might end up with 2 precursors.</p> <p>3 We don't really have a model in a lot of 4 ovarian cancers where you can follow a precursor 5 all the way through to -- what we think is a 6 precursor all the way through to the final tumor. 7 We just -- we don't really have a lot of data on 8 those in-between steps.</p> <p>9 So it was very, very interesting when they 10 discovered these STIC lesions in the fallopian 11 tube fimbria that had P53 mutations. It was 12 pretty compelling that these might be the 13 precursor lesions to serous -- high-grade serous 14 carcinomas.</p> <p>15 Now, are all high-grade serous carcinomas 16 caused by STIC lesions or are they all -- is a 17 STIC lesion a precursor to all serous -- 18 high-grade serous carcinomas? I don't think we 19 know that.</p> <p>20 Q. Do you know of any data associating 21 high -- excuse me, associating chronic 22 inflammation or injury with the development of 23 STIC lesions?</p> <p>24 A. So, again, I think the literature is 25 still evolving with this -- these STIC lesions.</p>
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<p>1 carcinoma in situ in the breast. There's 2 literature that debate about is ductal carcinoma 3 in situ a true cancer or is it a risk factor for 4 cancer, and what is the meaning of treatment for 5 DCIS in the breast? And I would say that that's 6 sort of analogous to STIC lesions in the 7 fallopian tube.</p> <p>8 Q. Okay. Do you agree that most 9 high-grade serous carcinomas arise from the 10 endometrial cells in the fallopian tube?</p> <p>11 A. High-grade --</p> <p>12 Q. Epithelial cells in the fallopian tube. 13 Excuse me.</p> <p>14 A. So, again, we -- this was something 15 that the medical community really struggled with, 16 trying to find the precursor lesions to a lot of 17 these tumors.</p> <p>18 And for a lot of years it was thought that 19 maybe serous carcinomas derived from what are 20 called epithelial inclusion cysts, so, basically, 21 the thought was that during ovulation, you're 22 disrupting the surface epithelium of the ovary 23 and when the ovary sort of heals itself, you get 24 this invaginated epithelium within the ovary and 25 that maybe because of inflammatory response to</p>	<p>1 Q. Sorry. Were you finished? I don't 2 want to interrupt you if you're thinking.</p> <p>3 A. No, I'm thinking.</p> <p>4 Again, I don't think we really have the data 5 on where these STIC lesions are coming from.</p> <p>6 Q. As part of your literature review for 7 your MDL report, did you search specifically for 8 papers that might be linking or associating 9 chronic inflammation with early precursor lesions 10 to serous invasive carcinomas or high-grade 11 serous carcinomas?</p> <p>12 A. I was certainly looking for literature 13 with the association of inflammation with ovarian 14 cancer.</p> <p>15 Q. With -- did you look specifically at 16 the various subtypes of ovarian cancer?</p> <p>17 A. Yes.</p> <p>18 Q. Is there a particular subtype of 19 ovarian cancer that you think is associated with 20 talc use?</p> <p>21 A. So most of the epidemiology literature 22 show the highest association with high-grade 23 serous invasive carcinoma.</p> <p>24 Q. When you say "highest association," are 25 you talking about strength of association?</p>

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<p>1 A. I'm talking about the -- for example, 2 on the cohort studies, they found an association 3 with high-grade serous carcinoma. 4 And in a lot of the case-control studies, 5 when they looked at tumor subtype, a lot of those 6 tumors were serous carcinomas. Now, some of them 7 broke them out by relative risk by subtype; some 8 of them didn't. I'd have to look at the papers. 9 Q. Do you remember which cohort study 10 found an association with high-grade serous 11 carcinoma? 12 A. I believe the Nurses' Health Study. 13 I'd have to look at it to see the numbers. 14 Q. Was there more than one cohort study 15 that you recall associated talc use with 16 high-grade serous carcinoma? 17 A. I'd have to look at them just to be 18 sure, but the one that I remember is the Nurses' 19 Health Study. 20 Q. Are there any other subtypes, 21 histologic types, of ovarian cancer that you 22 believe are associated with talc use? 23 A. Well, I think talc use -- I think talc 24 use could be associated with the -- any type of 25 surface epithelial cancer. That seems to bear</p>	<p>1 A. So I think the most consistent finding 2 is with high-grade serous carcinoma, but there's 3 data for the other types of surface epithelial 4 carcinomas. 5 Q. And what are the surface types of 6 carcinomas? 7 A. So they're endometrioid and clear cell, 8 and mucinous less so than, I believe, the 9 endometrioid and clear cell, although I believe, 10 again, in the 2010 Nurses' Health -- is that -- 11 I'd have to go back -- I -- there was a mention 12 of mucinous -- I'm not absolutely sure it was the 13 Gates 2010, but there was a mention of an 14 increased risk of mucinous in one of those 15 studies. 16 Q. Do you agree that the different 17 histologic subtypes of epithelial ovarian cancer 18 are likely to have different genetic causes? 19 A. I know they're associated with 20 different genetic mutations. 21 Q. Do they develop along distinct 22 molecular genetic pathways? 23 A. That's what the literature suggests at 24 this point. 25 Q. Do they behave differently?</p>
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<p>1 out in the epi data. They've certainly seen an 2 association with different types of surface 3 epithelial cancers in the epi data, the strongest 4 association being with the serous invasive. 5 Q. Have you seen any data supporting an 6 association with talc use and a low-grade serous 7 carcinoma? 8 A. I'd have -- again, I'd have to look at 9 the different studies to break it out, but I know 10 there was a study that found an increased risk 11 with serous borderline carcinomas. I'd have to 12 look through the individual data sets. 13 Q. And serous borderline -- are -- serous 14 borderline tumors are not carcinomas; correct? 15 A. Sorry. I -- serous borderline tumors, 16 yes. I misspoke. 17 Q. And you don't remember what study that 18 was that associated talc use with serous 19 borderline tumors? 20 A. I would have to look at the data -- or 21 the study. 22 Q. So do your opinions in this case apply 23 equally to all histologic subtypes of ovarian 24 cancer or are there specific subtype or subtypes 25 that you are opining are caused by talc?</p>	<p>1 A. So the high-grade surface epithelial 2 carcinomas have a more aggressive pathway or 3 presentation. The low-grade surface endothelial 4 carcinomas tend to have a more indolent 5 progression. 6 Q. You've used the term "surface 7 epithelial carcinomas" and I haven't seen that 8 term generally used in the literature. 9 When you talk about surface epithelial 10 carcinomas, are you talking about serous or are 11 you talking about endometrioid or are you talking 12 about clear cell? Mucinous? 13 A. Epithelial carcinomas. 14 Q. That would encompass all of those, 15 wouldn't it? Wouldn't surface epithelial 16 carcinomas encompass mucinous, clear cell, 17 endometrioid, and serous subtypes? They're all 18 epithelial ovarian cancers; correct? 19 A. Yes. That's what I'm referring to when 20 I -- because we also have germ cell tumors and 21 stromal tumors of the ovary. Those are much more 22 rare, and I'm not -- you know, I don't think 23 there's associations with those. So, yes, we're 24 talking about epithelial carcinomas, to be clear. 25 Q. Well, and just -- because I want to</p>

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<p style="text-align: right;">Page 86</p> <p>1 make sure your testimony is also clear. 2 So if we could, if you could use the 3 specific subtype names, like serous or 4 endometrioid -- 5 A. Okay. 6 Q. -- or clear cell. That way there's no 7 confusion later on about what you intended. 8 So when you say -- let's see. Let me go 9 down. Sorry. 10 When you say "high-grade surface epithelial 11 carcinomas," are you talking about high-grade 12 serous carcinomas? 13 MR. ROTMAN: Objection. You're asking 14 her to reflect back on all of her prior answers 15 to all of your prior questions, whether she was 16 referring to the same thing in each one? 17 Q. Do you understand my question? 18 A. I'd have to figure out what answer 19 you're talking about, but -- 20 Q. So you just -- just a few questions 21 ago, you answered -- I said, "Do the different 22 types -- histologic types develop along the same 23 molecular genetic pathways?" 24 You said, "That's what the literature 25 suggests at this point."</p>	<p style="text-align: right;">Page 88</p> <p>1 Does that make sense? 2 A. Okay. Yes. Okay. 3 Q. Okay. All right. So let me ask my 4 question that I asked a little while again, and 5 you tell me -- you can answer it again with the 6 terminology. 7 Do the different histologic subtypes of 8 ovarian cancer behave differently? 9 A. Yes. Again, the high-grade ones 10 generally behave differently than the low-grade 11 ones. 12 Q. Okay. Do endometrioid and clear cell 13 carcinomas behave differently from high-grade 14 serous carcinomas? 15 A. The high-grade serous carcinomas tend 16 to behave more aggressively. 17 Q. Do low-grade serous carcinomas behave 18 differently from endometrioid, clear cell, and 19 high-grade serous carcinomas? 20 A. They tend to be less aggressive. They 21 all tend to be less aggressive than the 22 high-grade serous carcinomas or other high-grade 23 carcinomas of the ovary. 24 Q. And are they thought to each have 25 different cells of origin?</p>
<p style="text-align: right;">Page 87</p> <p>1 I asked, "Do they behave differently?" 2 And then you responded, "So the high-grade 3 surface epithelial carcinomas have a more 4 aggressive pathway or presentation. The 5 low-grade surface epithelial carcinomas tend to 6 have a more indolent..." 7 Were you talking about high-grade serous and 8 low-grade serous carcinomas? 9 A. I was talking -- sorry. I was talking 10 about high-grade serous carcinomas, yeah. And we 11 also have sort of undifferentiated carcinomas 12 that are also considered high grade. 13 Q. Okay. And were you talking about 14 low-grade serous carcinomas when you said 15 "low-grade surface"? 16 A. No. So "surface" doesn't really refer 17 to cell type; it's just sort of a -- 18 Q. Right. 19 A. -- an umbrella term for the epithelial 20 carcinoma. 21 Q. Right, which is my point. I just 22 wanted to be clear. When you say "surface" -- 23 A. Yes. 24 Q. -- could you instead use the actual 25 cell type.</p>	<p style="text-align: right;">Page 89</p> <p>1 A. Again, we're not entirely sure where 2 these tumors are arising from, particularly with 3 mucinous carcinomas. I think mucinous carcinomas 4 and there's also a type transitional cell, which 5 is very, very rare, and most of the literature, 6 when it comes to the epi data, don't really 7 discuss transitional cell. 8 But putting that aside, mucinous carcinomas 9 we have, I think, the least amount of data on 10 where they are actually arising from. Clear cell 11 and endometrial carcinomas have an association 12 with endometriosis, but, again, you know, are all 13 cases of endometrioid and clear cell carcinomas, 14 are they all arising from endometriosis? I don't 15 think I can say that. I don't think we know for 16 sure. 17 And serous carcinomas, we talked about the 18 precursor lesions and the fallopian tubes. 19 So there are differences where we think the 20 tumors are arising from, but, again, I don't 21 think we have absolutes where we can definitively 22 say, you know, this particular tumor in this 23 particular woman arised [sic] from this precursor 24 or... 25 Q. Okay. And do you know if the different</p>

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<p style="text-align: right;">Page 90</p> <p>1 histologic subtypes have been associated in the 2 epidemiologic literature with different risk 3 factors? 4 A. Yes. Again, I think we touched on some 5 of that before. There is an association with 6 endometrioid and clear cell with endometriosis 7 and obesity. 8 Mucinous carcinomas have shown to be 9 associated in some studies with a smoking 10 history. 11 High-grade serous carcinomas, it's a little 12 bit harder. We know that BRCA1 and BRCA2 13 patients have an increased risk. 14 Q. Now that we're on that topic of 15 genetics, do you know what proportion -- 16 currently, what is believed to be the proportion 17 of ovarian cancers that are caused by germline 18 mutations? 19 A. Off the top of my head, I think -- do I 20 have that in my report? But I -- I'm thinking 21 it's 10 to 20 percent, but that's off the top of 22 my head. 23 Q. Have you seen any research coming out 24 of Seattle Cancer Care Alliance over the last 10 25 or 15 years that indicates the number could be as</p>	<p style="text-align: right;">Page 92</p> <p>1 Q. -- this is an article by Karen 2 Malmberg, et al., entitled "Serous tubal 3 intraepithelial carcinoma, chronic fallopian tube 4 injury, and serous carcinoma development," and it 5 was in Virchows Archives, March of 2016. 6 MR. TISI: What did you mark this? I'm 7 sorry. 8 MS. AHERN: I marked this one 9. Thank 9 you. No -- yes, 9. 10 MR. TISI: Oh, I'm sorry. 11 MS. AHERN: That's okay. 12 Q. Do you recall if you've ever reviewed 13 this article? 14 A. It's possible. It's certainly possible 15 that I have seen this before in just my daily 16 practice. I don't believe I cited it in any of 17 the references that I can remember, but it's 18 highly possible that I've seen it. 19 Q. Do you see the first page that -- you 20 can just skip if you want, take your time reading 21 it if you'd like, but the authors conclude in 22 their study that there is no correlation with 23 chronic tubal injury or inflammation with the 24 development of STIC lesions or the existence of 25 STIC lesions.</p>
<p style="text-align: right;">Page 91</p> <p>1 high as a quarter of all ovarian cancers being 2 linked to germline mutations? 3 A. That would roughly fit with what I just 4 said, 10 to 20 percent. I can't say for sure 5 that I have seen that. I might have. But it 6 fits with what I remember. 7 Q. I had asked you earlier if you had 8 reviewed any literature relating to inflammatory 9 conditions and associations with early STIC 10 lesions. 11 And you -- and, I'm sorry, I don't want to 12 misstate your response. What was your response 13 to that? 14 A. Had I reviewed literature? Yes, I've 15 seen literature. 16 Q. Okay. 17 (Article entitled "Serous tubal 18 intraepithelial carcinoma, chronic 19 fallopian tube injury, and serous carcinoma 20 development" marked Exhibit 9.) 21 BY MS. AHERN: 22 Q. I'm handing you what's been marked as 23 Exhibit 9 to your deposition. And this is -- 24 MS. AHERN: I don't know if anyone else 25 wants one.</p>	<p style="text-align: right;">Page 93</p> <p>1 Do you see that? 2 A. No. Can you -- I'm sorry, can you 3 point to me -- 4 Q. Oh, sure. 5 A. -- where? 6 Q. Do you see the abstract, if you carry 7 it over to the second column? 8 A. Mm-hmm. Yes. 9 Q. It says, "STIC and invasive cancer were 10 seen more often in the older patients than in the 11 younger patients"? 12 A. Mm-hmm. 13 Q. This study is -- small study, no 14 correlation with chronic tubal injury or 15 inflammation was identified. 16 A. Yes, with the caveat -- that was a 17 conclusion with the caveat that it was a small 18 study. 19 Q. Have you -- as a gynecologic 20 pathologist or a pathologist who has subspecialty 21 training in gynecologic malignancies, how often 22 do you see chronic -- or evidence of chronic 23 inflammation surrounding STIC lesions? 24 Or strike that. How often do you see STIC 25 lesions?</p>

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<p>1 A. On -- certainly, I can't give you a 2 number. I've certainly made the diagnosis and 3 see it -- I can't give you a number of how many 4 times. 5 Q. Have you ever been involved in a study 6 looking specifically at STIC lesions and 7 high-grade serous carcinomas? 8 A. I have not been involved in a study, 9 no. 10 Q. Have you ever seen evidence of chronic 11 inflammation with a STIC lesion? 12 A. Off the top of my head, I am not sure. 13 It's possible, but I can't really answer that off 14 the top of my head. 15 Q. How often do you see chronic 16 inflammation in the fallopian tubes associated 17 with high-grade serous carcinoma? 18 A. You can certainly see it, but it sort 19 of goes along with the discussion that we had 20 before. You can see chronic inflammation within 21 the tumor, as well. 22 And so I think, you know, the literature 23 is -- the research is ongoing as to, you know... 24 Q. So once the tumor -- once there's a lot 25 of tumor burden in the abdominal cavity, it's</p>	<p>1 looks -- 2 MR. ROTMAN: Just so the record is 3 clear, when you said "this," do you want to 4 identify it? 5 A. Sorry. The fourth edition belongs to a 6 colleague. The fifth edition is my own. 7 MS. AHERN: Okay. We'll get to that 8 one. I'll mark that next. 9 Q. There is a photocopy here, "Blaustein's 10 Pathology of the Female Genital Tract, Fourth 11 Edition," Pages 300 and -- well, Page 376, 12 Page 539, Page 540, 648, 1216, 1217, 1218. 13 Is this a copy -- are these copies that you 14 made? 15 A. Yes. 16 Q. Okay. 17 MR. TISI: Do you have a stapler? 18 Otherwise I'll get one. 19 MS. AHERN: No, I don't have one. 20 MR. TISI: No, I'll go get one. 21 BY MS. AHERN: 22 Q. Can you tell me why you made those 23 copies? 24 A. I made them because it was easier than 25 lugging around a whole textbook. That's why I</p>
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<p>1 difficult to tell where the inflammation is 2 coming from or what started it; is that correct? 3 A. Well, if there's chronic inflammation 4 in the tumor, it's likely the tumor has something 5 to do with the chronic inflammation. 6 But, again, you know, as we talked about 7 before, I think sometimes it is difficult to 8 tell. 9 MS. AHERN: Okay. Housekeeping matters 10 before I forget. 11 Let me go ahead somehow and mark -- 12 let's mark -- we can remove this later -- 13 "Blaustein's Pathology of the Female Genital 14 Tract," Fourth Edition, as Exhibit 10 to your 15 deposition. 16 ("Blaustein's Pathology of the 17 Female Genital Tract," Fourth Edition, 18 marked Exhibit 10.) 19 BY MS. AHERN: 20 Q. And, Doctor, you brought this textbook 21 with you today. 22 Is this your textbook? 23 A. That particular copy is not. That's my 24 coworker's copy. This copy is mine (indicating). 25 Q. Okay. And inside this, you have what</p>	<p>1 Xeroxed them. But -- 2 Q. You had to bring it anyway. 3 Sorry. Go ahead. 4 A. But the particular pages that I copied 5 are ones that talk about granulomatous reactions 6 to talc in the female reproductive system. 7 Oh, sorry. Okay. 8 MS. AHERN: Okay. We'll go ahead and 9 mark those copies as Exhibit 10 to your 10 deposition. 11 Q. And just to confirm -- 12 MS. AHERN: Sorry. Are we on 10 or 11? 13 We're on 11. Thank you. 14 Q. As a -- 15 MR. TISI: Is this the next one? 16 MS. AHERN: Yeah. Hold on. I'm going 17 to clarify it. 18 Q. So this photocopy that you made from 19 Blaustein's came from the fourth edition? 20 A. Correct. 21 Q. The textbook that we have here marked 22 as Exhibit 10. 23 A. (Witness nodded.) 24 Q. Okay. So Exhibit 11 are photocopies of 25 specific pages from Exhibit 10, which is</p>

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<p style="text-align: right;">Page 98</p> <p>1 Blaustein's Pathology of the Female Genital 2 Tract, Fourth Edition. 3 (Excerpt from "Blaustein's 4 Pathology of the Female Genital Tract," 5 Fourth Edition, marked Exhibit 11.) 6 BY MS. AHERN: 7 Q. Okay. And can you tell me, with 8 Exhibit 11, the specific information that you 9 found relevant to your opinions in this case? 10 A. Okay. So on Page -- 11 MR. ROTMAN: You marked the copy as 12 Exhibit 11 and the book as Exhibit 10? 13 MS. AHERN: Mm-hmm. 14 MR. ROTMAN: Okay. 15 A. Okay. You have to bear with me, 16 because I don't have any highlights or anything, 17 so I have to find it. 18 So Page 376, right down -- okay. The last 19 paragraph under "Zanko Granulomatous 20 Inflammation," it says, "Rarely, talc or another 21 foreign substance may elicit a foreign-body 22 reaction in the endometrium. Talc may be 23 introduced into the endometrial cavity by 24 instruments contaminated with talcum powder or by 25 gloves during a pelvic examination. Patients may</p>	<p style="text-align: right;">Page 100</p> <p>1 evidence, and it shows that talc can cause 2 granulomatous or chronic inflammation in the 3 female reproductive tract. 4 Q. And how is uterine cancer related to, 5 for instance, high-grade serous carcinoma of the 6 ovary? 7 A. Again, this is just evidence that talc 8 can cause chronic inflammation and granulomas in 9 the endometrium, which I think is another piece 10 of evidence that talc can cause chronic 11 inflammation and granulomatous inflammation in 12 the female reproductive tract. 13 Q. Doctor, shouldn't talc -- based on the 14 literature that we have available to us over the 15 last 50 years, shouldn't talc induce that 16 response in any tissue that it's found in? 17 A. Well, again, different tissues will 18 respond in different ways, but I think it also 19 depends -- well, I'll just... 20 Q. Well, as a pathologist -- 21 MR. ROTMAN: Wait. Wait. Are you 22 done? 23 MS. AHERN: Are you done? 24 THE WITNESS: I think so. 25 Q. Okay. So as an anatomic pathologist</p>
<p style="text-align: right;">Page 99</p> <p>1 be asymptomatic or may have menorrhagia. 2 Microscopically, the extent of the granulomatous 3 inflammatory reaction depends on the quantity of 4 talc inoculated. The infiltrate is characterized 5 by histiocytes and foreign-body multinucleated 6 giant cells surrounding the talc crystals, along 7 with lymphocytes and plasma cells. The crystals 8 appear as refractile, birefringent, needle-like, 9 or fan-shaped splinters in polarizing light." 10 Then on Page 530 -- 11 Q. Sorry. Let me just -- let's take this 12 in order. 13 So what about that particular passage 14 informs your causation opinions regarding talc 15 and ovarian cancer, if at all? 16 A. So it is evidence that talc causes 17 foreign-body giant cell reaction and chronic 18 inflammation in the endometrium. 19 Q. And that is the uterine tissue; 20 correct? 21 A. That's the lining of the uterus, 22 correct. 23 Q. And how does that inform your opinions 24 regarding the development of ovarian cancer? 25 A. Well, I thought, again, it's a piece of</p>	<p style="text-align: right;">Page 101</p> <p>1 who knows something about granulomatous 2 reactions, shouldn't a foreign body produce a 3 foreign-body reaction in any tissue that it's 4 found in? 5 A. Not -- no, not always. Sometimes you 6 will have a foreign body that won't cause a 7 foreign-body giant cell reaction. It depends 8 on -- it depends on the particle, the foreign 9 body, the tissue it's in. You don't always see 10 that. And also the timing, when you're looking 11 at it, versus how long it's been there. 12 Q. Well, the timing is just more or less 13 when you observed it, not whether it occurred; 14 correct? 15 MR. ROTMAN: Objection. 16 A. So it's hard to know whether or not it 17 occurred -- if it had been there for a long time 18 and you're looking years, you know, in -- years 19 after it's been there, if you don't see a 20 granulomatous or chronic inflammation, that's not 21 evidence that it never occurred; it's just you're 22 not seeing it at that moment. 23 Q. Do you know of any -- any foreign 24 bodies that generate tissue-specific reactions? 25 A. Well, we -- I mean, we certainly have</p>

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<p>1 evidence with, say, viruses and bacteria that 2 respond differently -- certain tissues will 3 respond differently to different infections. 4 For esophageal cancer, there's some 5 literature to suggest that very hot liquids 6 increase your risk of esophageal cancer. So, 7 yes, certain tissues will respond differently to 8 different material. 9 Q. So my question was -- it might be just 10 a little simpler to think of just this 11 question -- do you know of any foreign bodies -- 12 I'm not talking about viruses and bacteria which 13 cause immune responses -- but foreign bodies that 14 generate a tissue-specific foreign-body reaction? 15 A. Well, it's sort of semantics. I mean, 16 viruses and bacteria -- that's why I answered the 17 way I did -- are foreign to -- and, certainly, 18 foreign bodies can elicit immune response. 19 That's why you see granulomatous reactions and 20 chronic inflammation. 21 So I guess I'm not -- I think I answered the 22 question. 23 Q. Pathologists distinguish the different 24 types of granulomatous inflammation based on the 25 cause of the inflammation; correct?</p>	<p>1 granulomas, which are caused by talc and 2 cornstarch and certain other inert-type 3 materials; correct? 4 MR. ROTMAN: Objection. 5 A. Again, you can have inflammation -- 6 granulomatous inflammation due to infection, you 7 can have granulomatous infection -- response due 8 to foreign bodies, and you can have granulomas in 9 certain diseases, like sarcoidosis or Crohn's 10 disease. 11 So in that respect, yes, we're categorizing 12 granulomas, but on a daily basis, other than that 13 type of breakdown, we're not subcategorizing 14 granulomas. 15 Q. But you are aware of the literature 16 that actually characterizes the different types 17 of granulomas and the types of cells that are 18 involved in the formation of those granulomas; 19 correct? 20 A. As far as foreign-body giant cells and 21 multinucleated giant cells and inflammatory 22 versus foreign body, yes. 23 Q. So, you know, a granuloma caused by 24 tuberculosis is going to be very different from a 25 granuloma caused by talc; correct?</p>
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<p>1 A. We look for -- if we see granulomatous 2 inflammation in tissue, we certainly look for a 3 potential cause. We want to rule out infection, 4 so if we see granulomas, we'll routinely do 5 special stains to rule out infection. Like we'll 6 do an acid-fast Bacillus stain for microbacteria. 7 We'll do fungal stains to rule out a fungal 8 infection that causes inflammation. 9 And then, of course, if we have -- if those 10 are negative and we're trying to figure out if 11 there's a foreign body within a granuloma, we can 12 use polarized light to try to find the foreign 13 body to identify it as a foreign-body giant cell 14 reaction. 15 But often you do have granulomatous 16 inflammation and you won't find fungi -- fungal 17 lesions -- fungal bodies or bacteria or 18 birefringent particles on them, so you don't 19 necessarily know why you have a granulomatous 20 inflammation. 21 Q. Pathologists categorize granulomatous 22 inflammation, don't they? They categorize it in 23 terms of the different types of immune granulomas 24 and the etiologic agents for those granulomas, 25 and over here somewhere are the foreign-body</p>	<p>1 MR. ROTMAN: Objection. 2 A. I would say not necessarily. In 3 microbacterial infections, you can have necrosis 4 within granulomas, but that doesn't mean that 5 you're not necessarily going to see necrosis in a 6 foreign-body granuloma. 7 Q. How often have you seen necrosis 8 associated with a foreign-body granuloma? 9 A. I'd say more commonly you see 10 necrotizing or necrotic granulomas in infectious 11 granulomas. 12 Q. There are different types of 13 macrophages that are involved, too, in 14 foreign-body granulomas and in immune granulomas; 15 correct? 16 A. As far as macrophages themselves and 17 multinucleated giant cells that can form 18 granulomas. 19 Q. There are different types, different 20 subtypes of macrophages that are involved in -- 21 A. Yes. 22 Q. -- those activities; correct? 23 A. Yes. 24 Q. Okay. So there are differences between 25 a foreign-body granuloma and an immune granuloma?</p>

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<p>1 A. There can be.</p> <p>2 Q. Well, there are, aren't there? I mean,</p> <p>3 there are papers that characterize these.</p> <p>4 A. Yes, but I'm -- yes. In the</p> <p>5 literature, yes. And -- but are we necessarily</p> <p>6 categorizing them when we're looking at a</p> <p>7 particular patient? We're looking for the cause</p> <p>8 of the granuloma, but we're not necessarily</p> <p>9 subcategorizing, is my point.</p> <p>10 Q. Understood.</p> <p>11 Oh, I'm sorry. We were talking about the</p> <p>12 pages that you copied from Blaustein's.</p> <p>13 What was the second page in that photocopy,</p> <p>14 Exhibit 11?</p> <p>15 A. Okay. So Page 539.</p> <p>16 Q. What was it on 539 that's relevant to</p> <p>17 your opinions in this case?</p> <p>18 A. Okay. I think it starts at the very</p> <p>19 bottom. I think it carries into Page 540, where</p> <p>20 it starts talking about foreign-body reactions in</p> <p>21 the -- this is diseases of the fallopian tube.</p> <p>22 So it starts, "Foreign material may be</p> <p>23 introduced into the tube in the course of</p> <p>24 gynecological investigation, especially</p> <p>25 hysterosalpingography, lubricant jelly, mineral</p>	<p>1 cancer, which is sort of the plausibility arm of</p> <p>2 the Bradford Hill. I think it's compelling</p> <p>3 evidence that we see that you can get</p> <p>4 granulomatous inflammation and some of these</p> <p>5 sections have mentioned lymphocytes and plasma</p> <p>6 cells in the tissue. I mean, I think it's a</p> <p>7 further piece of evidence that talc can cause</p> <p>8 these -- this type of inflammation in female</p> <p>9 reproductive market.</p> <p>10 Q. How often have you, in your career,</p> <p>11 seen a talc granuloma in gynecologic specimens?</p> <p>12 A. We don't routinely do -- perform</p> <p>13 polarized light microscopy on ovarian tumors,</p> <p>14 partly because you really need electron</p> <p>15 microscopy. You can -- with polarized light</p> <p>16 microscopy, you can tell that there's a foreign</p> <p>17 substance there, but that's pretty much as far as</p> <p>18 you can -- you can get. You need more testing to</p> <p>19 be able to determine what type of particle it is,</p> <p>20 usually. So we don't, in daily practice,</p> <p>21 routinely use polarized light microscopy.</p> <p>22 Now, it's entirely possible that, you know,</p> <p>23 in the course of my career, I've come across</p> <p>24 chronic inflammation or granulomas in an ovarian</p> <p>25 tumor that could have been due to talc that I</p>
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<p>1 oil, and starch and talc powder may cause lipoid</p> <p>2 or granulomatous salpingitis. Talc may cause</p> <p>3 mucosal or serosal granulomas. Examination of</p> <p>4 all granulomas or foreign-body reactions under</p> <p>5 polarized light is useful in the recognition of</p> <p>6 these processes."</p> <p>7 So, again, I'm just referencing the fact</p> <p>8 that talc can cause granulomatous reaction in the</p> <p>9 fallopian tube.</p> <p>10 Q. So another tissue that's exposed to</p> <p>11 talc forms the typical type of foreign-body</p> <p>12 response?</p> <p>13 A. That can form a granulomatous reaction.</p> <p>14 Q. Okay. And does that in any way inform</p> <p>15 your opinions on causation, other than</p> <p>16 granulomatous reactions occur?</p> <p>17 A. Well, so, again, it's another piece of</p> <p>18 evidence that talc can cause a granulomatous</p> <p>19 reaction within the female reproductive tract.</p> <p>20 Now, the fallopian tube, we know some -- has</p> <p>21 been indicated as a precursor site for certain</p> <p>22 high-grade serous carcinomas, so I think it's</p> <p>23 relevant.</p> <p>24 But, again, you know, we're talking about</p> <p>25 mechanisms that talc may eventually cause ovarian</p>	<p>1 didn't polarize so I didn't see particles, I</p> <p>2 guess.</p> <p>3 Q. So let me back up and just ask you:</p> <p>4 How often in your career have you seen</p> <p>5 foreign-body granulomas? Regardless of whether</p> <p>6 you've identified the particle in the granuloma,</p> <p>7 how often have you seen foreign-body granulomas</p> <p>8 in gynecologic specimens? Not just tumors, but</p> <p>9 any gynecologic specimens you've reviewed.</p> <p>10 A. No, I understand.</p> <p>11 Q. Okay.</p> <p>12 A. You can certainly see granulomas -- how</p> <p>13 often, I can't give you a number; that would just</p> <p>14 be wildly guessing -- but you can see granulomas</p> <p>15 in the endometrium. You can see them in</p> <p>16 different types of tumor.</p> <p>17 Sometimes it's -- you'll see granulomas, but</p> <p>18 you won't see a particle, so you don't know for</p> <p>19 sure if it's a foreign-body granuloma; you just</p> <p>20 see the granuloma because you're not using</p> <p>21 polarized light microscopy on it.</p> <p>22 MR. KLATT: Object. Nonresponsive.</p> <p>23 MS. AHERN: Same.</p> <p>24 Q. So how often, though, in your career --</p> <p>25 you can give me an estimate -- have you seen</p>

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<p style="text-align: right;">Page 110</p> <p>1 foreign-body granulomas in gynecologic specimens? 2 MR. ROTMAN: Objection. 3 Q. I'm not talking about immune 4 granulomas, but just foreign-body granulomas. 5 We'll start there. 6 MR. ROTMAN: Objection. You've asked 7 that question. She's answered it. 8 A. So, again, I've seen granulomas in my 9 career in the female reproductive tract, but I 10 don't -- pathologists don't routinely use 11 polarized light microscopy in that instance to 12 look for foreign bodies. 13 Q. Okay. So are you done? 14 MR. ROTMAN: Can we take a break? 15 MS. AHERN: Not just yet. Let me 16 finish this line of questioning and then we can 17 take a break. Because we may want to -- what 18 time is it? 19 MR. ROTMAN: It's been an hour. 20 MS. AHERN: 11:30. If we go a little 21 bit longer, we can break for lunch if you want. 22 MR. ROTMAN: I just want to take a 23 break in the next few minutes. 24 MS. AHERN: Sure. 25</p>	<p style="text-align: right;">Page 112</p> <p>1 foreign body, you're not necessarily going to be 2 able to say whether or not it's a foreign-body 3 granuloma with absolute certainty unless you're 4 looking under polarized light microscopy. And 5 even then, you might not see it under polarized 6 light microscopy, because it depends on the 7 section of the tissue you're looking at and -- 8 Q. Okay. Thank you. 9 And if you see a foreign-body response in 10 tissue, do you then go one step further and 11 polarize to see if you can identify whether 12 that's got a foreign body in it? 13 A. It certainly depends on the situation. 14 So, for example, in cases where there's been 15 a surgery and they've taken out more tissue after 16 surgery, you might be looking for polarizable 17 foreign body. Often, you can see a suture on 18 light microscopy. But, yeah, we do -- depending 19 on the situation, we will use polarized light 20 microscopy to find foreign bodies. 21 MR. ROTMAN: Okay. 22 Q. How often do you polarize specimens 23 where you've found a foreign-body response? How 24 often do you do that? 25 A. I think -- I think I tried to come up</p>
<p style="text-align: right;">Page 111</p> <p>1 BY MS. AHERN: 2 Q. Doctor, are you able, as a -- as a 3 pathologist, under regular light microscopy to 4 identify a foreign-body granuloma? Not the 5 content, just the foreign-body granuloma. 6 A. I would say it depends on the specific 7 granuloma. Sometimes, for example, in epidermal 8 inclusion cysts, you can see the keratin under 9 light microscopy that's causing the reaction, but 10 you don't always -- you won't always necessarily 11 see a particle. They're very small. And unless 12 you're looking specifically for polarizable 13 birefringent particles, you're not going to see 14 it just with regular light microscopy. 15 Q. So my question wasn't -- and I thought 16 I was specific -- my question wasn't whether or 17 not you could see the particle; my question was: 18 You should be able to see the foreign-body 19 response in terms of multinucleated giant cells. 20 Do you -- can you see that under regular 21 light microscopy? 22 A. Well, so you're categorizing it as a 23 foreign-body granuloma. What I'm saying is you 24 can see granulomas, of course, under light 25 microscopy. But if you're not looking for a</p>	<p style="text-align: right;">Page 113</p> <p>1 with an estimate. I think I have it in my 2 report, actually, in the beginning. 3 Yes. So I estimated that I use polarized 4 light microscopy for this purpose, which is 5 identifying foreign material to explain an 6 inflammatory reaction, I estimated about twice a 7 month. It's an estimate. 8 And I -- well, that was -- actually, I was 9 referring to calcium oxalate crystals in breast 10 biopsies. That's different. So it's not 11 uncommon, let's put it that way, but I can't 12 really give you a -- an estimate. 13 Q. What was the estimate for breast 14 tissue? 15 A. I think it was twice a month, is what I 16 said. 17 Q. So compared to looking for calcium 18 crystals in breast tissue twice a month, how 19 often in gynecologic specimens do you look for 20 foreign bodies? 21 A. I would say slightly less than that. 22 Q. Maybe once a month, maybe less than 23 that? 24 A. Once a month is probably a good 25 estimate, I guess.</p>

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<p style="text-align: right;">Page 114</p> <p>1 Q. Do you know, based on your review of 2 the epidemiologic literature, what proportion of 3 women are said to use talc? 4 A. I believe I've seen in some of the 5 literature -- it depends on the population, I 6 think. I think I saw -- well, again, I'd have to 7 pull out the papers to be absolutely certain, but 8 I remember there was a reference to 9 African-American women, about 50 percent of them 10 using talc. 11 Q. Would you say that in 50 percent of the 12 gynecologic specimens you review, you find 13 foreign-body granulomas or granulomas? 14 A. Well, I wouldn't necessarily expect -- 15 I wouldn't expect to, just because, you know, 16 again, we're looking at an ovarian tumor at a 17 very particular point in time. 18 How many granulomas -- how much talc is 19 getting to the ovary, we don't -- we don't know 20 how much talc is getting to the ovary. We know 21 it's been found there, we know it can get there, 22 but we don't know with how much use, how much is 23 actually getting there. 24 So we wouldn't necessarily find a lot of 25 granulomas in ovarian tissue of women that use</p>	<p style="text-align: right;">Page 116</p> <p>1 I mean, it's not -- it's not frequent that 2 you're going to find foreign-body giant cell 3 reactions in tissue, but, again, it doesn't mean 4 that they weren't there. Maybe -- 5 Q. And this is based just on your 6 experience. I know that -- I don't want you to 7 guess about what might have been there -- 8 A. Yeah, I'm -- 9 Q. -- but based on your experience as a 10 practicing pathologist. 11 A. It would just be a pure guess at this 12 point. I couldn't give you an accurate number. 13 Q. Do you see foreign-body reactions in 14 50 percent of the gynecologic specimens or cases 15 that you review? 16 MR. ROTMAN: Objection. 17 A. I would say it's less than 50 percent. 18 Q. Is it less than 25? 19 A. I would say less than 25. 20 Q. Less than ten? 21 A. Probably less than ten. 22 Q. Less than five? 23 A. That's where I'm not exactly sure. 24 Q. Okay. 25 MS. AHERN: All right. We can go ahead</p>
<p style="text-align: right;">Page 115</p> <p>1 it, because we don't know exactly how much is 2 getting there or we don't know how long those 3 granulomas are there once the tissue is in the 4 ovary. 5 I mean, 20 years later, when you're looking 6 at the -- at the ovary for a talc particle that's 7 been there, we don't know if the granuloma would 8 still be there or the chronic inflammation would 9 still be there. 10 Q. And my question wasn't specific to 11 ovarian tissue; it was just gynecologic 12 specimens. 13 Because you review more than ovarian tissues 14 when you're looking at gynecologic samples; 15 correct? 16 A. Yes. 17 Q. So looking at all of your gynecologic 18 specimens, your vaginal, vulvar, endometrial, 19 tubal, ovarian, I guess omentum might fall in 20 there, how often do you identify foreign bodies 21 or foreign-body granulomas? 22 A. I would have to be -- a completely 23 ballpark guess, but, I don't know, maybe every -- 24 I'm really trying to figure out a somewhat 25 ballpark figure. It's tough.</p>	<p style="text-align: right;">Page 117</p> <p>1 and take a break. Thank you. 2 THE VIDEOGRAPHER: Here ends Media 2. 3 Off the record, 11:44 a.m. 4 (A recess was taken.) 5 THE VIDEOGRAPHER: Here begins Media 6 No. 3 in today's deposition of Sarah Kane, M.D. 7 Back on the record, 12:02 p.m. 8 BY MS. AHERN: 9 Q. All right. Doctor, can we go ahead and 10 keep moving through that photocopy, Exhibit 11. 11 Can you tell me what the next page was? 12 A. Okay. We just read from Page 540, I 13 believe, so the next one is Page 648. 14 Q. Okay. And tell me what on 648 caught 15 your eye. 16 A. Okay. It's the first paragraph under 17 "Noninfectious Granulomatous Peritonitis." So it 18 says, "Foreign material typically recognizable on 19 histologic examination can elicit a granulomatous 20 reaction on the peritoneum. Starch granulomas 21 from surgical gloves, douche fluid, and 22 lubricants typically incite a granulomatous and 23 fibrosing peritonitis. In occasional cases, the 24 inflammatory reaction may be a tuberculoid type 25 with KCS necrosis. The periodic acid shift (PAS)</p>

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<p style="text-align: right;">Page 118</p> <p>1 positive starch granules exhibit the 2 characteristic Maltese cross configuration" -- 3 THE COURT REPORTER: I'm sorry, you're 4 reading too fast. 5 THE WITNESS: I'm sorry. 6 A. "The periodic acid shift (PAS) positive 7 starch granules exhibits a characteristic Maltese 8 cross configuration under polarized light. Talc 9 was once an important cause of granulomatous and 10 fibrosing peritonitis because of its use as a 11 lubricant on surgical gloves and talc-induced 12 peritonitis has been described more recently in 13 drug abusers." I think that's kind of where it 14 stops. 15 Q. Okay. And how does that passage that 16 you just read inform your opinions in this case? 17 A. Well, again, it's just another -- 18 similar to the last pieces, this is the 19 peritoneum, so this is outside of the fallopian 20 tube. Once particles are outside of the 21 fallopian tube, they are in the peritoneum. 22 That's where the ovary is. And so it's 23 discussing foreign-body granulomatous reactions 24 in the peritoneum. 25 Q. And this question -- this passage that</p>	<p style="text-align: right;">Page 120</p> <p>1 head. 2 Q. And when you say "they" were looking 3 at, are you talking -- who are you talking about? 4 A. When the -- when the regulatory -- if I 5 recall -- did I put that in my report? -- they 6 removed -- I know that they removed starch from 7 surgical gloves because it was causing an 8 inflammatory reaction. 9 And they had started using starch more 10 commonly because talc had been removed from 11 surgical gloves for also causing inflammatory 12 reactions. 13 Q. And talc particles and cornstarch 14 particles cause the same foreign-body reaction in 15 the peritoneum and fibrosis; correct? 16 A. Well, again, they can cause a 17 granulomatous reaction, but they're 18 bioabsorbable, so it's not going to be -- you 19 know, when we're talking about talc, we're 20 talking about the talc in surgical gloves. And, 21 you know, talc is not bioabsorbable and it will 22 stay in the peritoneum longer than starch, which 23 is bioabsorbable. So it will -- the inflammation 24 will likely resolve more quickly. It's a 25 different -- it's a different type of reaction</p>
<p style="text-align: right;">Page 119</p> <p>1 you just read also mentions that starch granules 2 from surgical gloves -- 3 A. Yes. 4 Q. -- cause granulomatous and fibrosing 5 peritonitis, which is the same that they mention 6 talc use to. 7 Would you say that starch granules, then, 8 have the capacity to cause chronic inflammation 9 that can lead to cancer? 10 A. Starch can cause inflammatory 11 reactions, but it's a -- very different, in that 12 it's bioabsorbable, and so the particles are 13 absorbed in the body. And the literature hasn't 14 supported a link between starch and ovarian 15 cancer. 16 Q. How many studies have evaluated the 17 association between starch and ovarian cancer? 18 A. I couldn't say, off the top of my head, 19 how many. But I know, you know, they looked at 20 starch when they were evaluating whether or not 21 to remove it from surgical gloves, and they ended 22 up deciding to remove it from surgical gloves. 23 And I -- I think at that point they had done 24 a literature search. I don't think there was -- 25 I don't know how many studies off the top of my</p>	<p style="text-align: right;">Page 121</p> <p>1 because it's bioabsorbable. 2 Q. Well, they both cause granulomas; 3 right? 4 A. Mm-hmm. 5 Q. And they both cause fibrosis; correct? 6 A. They can cause fibrosis. 7 Q. Does the biodurability of the causative 8 agent determine how long fibrosis exists? 9 A. Well, the fibrosis is thought to arise 10 from the inflammatory process. And since -- I 11 don't know how much data is really there except 12 to say that starch is bioabsorbable and talc is 13 not. So talc is going to be available for an 14 inflammatory response more than a starch particle 15 will. 16 Q. Is the purpose of a foreign-body 17 granuloma to essentially wall off an irritant, a 18 foreign body, from the rest of the tissue to 19 prevent damage? 20 A. That can be one reason. 21 Another reason is if the particle is large 22 enough and one macrophage can't handle it because 23 of its size, it will sort of recruit more 24 macrophages to the area to try to digest the 25 foreign material, which is not going to -- they</p>

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<p style="text-align: right;">Page 122</p> <p>1 won't be able to digest the talc particle. 2 Q. If they can't digest the particle, 3 these macrophages will fuse to form a 4 multinucleated giant cell and surround the 5 particle to basically encapsulate it and prevent 6 it from harming the surrounding tissue; correct? 7 A. It's possible that they would, yes, 8 they would recruit more macrophages and 9 potentially do that. 10 Q. Isn't that the purpose of a 11 foreign-body granuloma? 12 A. So, again, you can get well-formed -- 13 you can get well-formed encapsulated granulomas. 14 You can also get sort of poorly formed granulomas 15 that are -- when more macrophages have been 16 recruited to that site. 17 You can get a -- you can get a histiocytic 18 reaction that isn't a well-formed granuloma in 19 the sense that you're talking about, where it's 20 kind of walling off the foreign body. You can 21 get histiocytic reactions that aren't as well 22 formed like that. 23 Q. But we're just talking about the actual 24 granuloma itself, those particles that do result 25 in a well-formed granuloma.</p>	<p style="text-align: right;">Page 124</p> <p>1 macrophages are continuously recruited to 2 foreign-body granulomas? 3 A. I know that I've read it in the course 4 of my daily practice. I can search at some point 5 for it, but I know that that's the case, because 6 I know that macrophages, again, have a certain 7 lifespan. 8 But, you know, again, the inflammatory 9 response, we also don't know how long that 10 inflammatory response is going to be there for 11 sure. Is it possible that at some point the 12 granuloma resolves and you get some fibrosis and 13 the talc particle or whatever particle is there 14 remains? I think that's possible and likely, in 15 fact, because you do see resolution of granulomas 16 with fibrosis. 17 Q. Is fibrosis associated with the 18 development of ovarian cancer? 19 A. There hasn't -- there hasn't been a 20 lot -- again, the causes of ovarian cancer are 21 sort of -- the literature and the research is 22 still bearing all of it out, but from what I know 23 of the literature, I don't think that they found 24 fibrosis itself being an increased risk factor 25 for ovarian cancer.</p>
<p style="text-align: right;">Page 123</p> <p>1 Once that granuloma has formed, it can 2 persist for many years, can't it, without 3 damaging the surrounding tissue? 4 MR. ROTMAN: Objection. 5 A. I think it would depend. Macrophages 6 have a certain lifespan, so it's going to be 7 constantly recruiting different macrophages to 8 that site. 9 So I don't think we can say for certain that 10 the -- in fact, I think the body is still 11 reacting to that foreign body if it's still 12 recruiting new macrophages in. 13 Q. Do you know that for a fact based on 14 your reading of the literature of granulomas, 15 that that's the mechanism behind a foreign-body 16 granuloma, as opposed to an immune granuloma? 17 A. What I'm saying is -- is that 18 macrophages have a certain shelf life, and so 19 they will constantly recruit new macrophages to 20 that area. 21 Now, whether or not there's an exposure in 22 that particle while it's in that process, I don't 23 think we can definitively say. 24 Q. Can you cite to any papers that support 25 your understanding of that process whereby</p>	<p style="text-align: right;">Page 125</p> <p>1 Q. Is fibrosis associated with chronic 2 inflammation? 3 A. It can be, yeah. Chronic inflammation 4 can lead to fibrosis. 5 Q. Do you know of any literature that has 6 linked talc granulomas introduced into the body 7 through the use of talc-dusted surgical gloves 8 with any sort of cancer? 9 A. So we know that talc can -- there are 10 studies that have shown talc in the ovaries, and 11 we know that chronic inflammation has been 12 implicated in cancer. 13 So if talc can reach the ovaries -- and we 14 also have evidence that talc causes chronic 15 inflammation. So if talc reaches the ovary, I 16 think it's a plausible mechanism for talc from 17 surgical gloves to cause an inflammatory reaction 18 and lead to cancer. I think that's plausible. 19 And, again, that's the plausibility arm of 20 it. You know, that's a piece of the general 21 causation opinion, but, you know, they're still 22 piecing together a lot of the etiology of ovarian 23 cancer. 24 Q. Then why -- 25 MR. KLATT: Objection, nonresponsive.</p>

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<p>1 MS. AHERN: Nonresponsive, yeah.</p> <p>2 Q. Doctor, why are you so sure, then, that</p> <p>3 talc causes ovarian cancer?</p> <p>4 A. It's --</p> <p>5 MR. ROTMAN: Objection.</p> <p>6 A. So I can lay out to you my methodology.</p> <p>7 It's in the report. I did very in-depth,</p> <p>8 extensive review of the literature, which</p> <p>9 included the epi studies, animal studies, and</p> <p>10 biologic studies.</p> <p>11 And I think -- well, I know that the epi</p> <p>12 studies have been very consistent with the</p> <p>13 increased risk associated with talcum powder</p> <p>14 product usage -- I'm talking about talcum powder</p> <p>15 product, what's in the bottle -- and perineal</p> <p>16 talc application with ovarian cancer.</p> <p>17 And I think if you're looking at -- if you</p> <p>18 go through the methodology that I used and you're</p> <p>19 looking at the Bradford Hill analysis, which I've</p> <p>20 laid out in the report, I've come to the</p> <p>21 professional -- you know, my professional</p> <p>22 judgment is that the talcum powder products --</p> <p>23 weighing everything, that talcum powder products</p> <p>24 cause ovarian cancer.</p> <p>25 And I know -- and, interestingly, about</p>	<p>1 MS. AHERN: No. We're going back to</p> <p>2 this question.</p> <p>3 MR. ROTMAN: Okay. That's fine.</p> <p>4 So you're asking her again a question</p> <p>5 that she previously answered.</p> <p>6 MR. KLATT: No --</p> <p>7 MS. AHERN: I'm interested in --</p> <p>8 MR. KLATT: -- a question she didn't</p> <p>9 answer.</p> <p>10 MS. AHERN: -- the question she didn't</p> <p>11 answer first.</p> <p>12 BY MS. AHERN:</p> <p>13 Q. Which is: "Do you know of any</p> <p>14 literature that has linked talc granulomas</p> <p>15 introduced into the body through the use of</p> <p>16 talc-dusted surgical gloves with any sort of</p> <p>17 cancer?"</p> <p>18 Do you know or not know of any literature</p> <p>19 that supports that?</p> <p>20 A. Well, first of all, I think we're</p> <p>21 talking about -- you're talking about surgical</p> <p>22 glove talc, right, which is pharmaceutical-grade</p> <p>23 talc, which is different from the talcum powder</p> <p>24 product that I'm opining about.</p> <p>25 And we know that these talc particles can</p>
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<p>1 three weeks after I wrote my report, there was</p> <p>2 the Health Canada report that, in reading their</p> <p>3 methodology and the literature that they</p> <p>4 reviewed, was very similar to what I reviewed and</p> <p>5 my methodology. And they came to the same</p> <p>6 conclusion.</p> <p>7 MR. KLATT: Objection.</p> <p>8 MS. AHERN: Objection. Nonresponsive.</p> <p>9 Q. Doctor, my question was: Do you know</p> <p>10 of any literature that has linked -- sorry.</p> <p>11 My first question we're going to go back to</p> <p>12 now is: Do you know of any literature that has</p> <p>13 linked talc granulomas introduced into the body</p> <p>14 through the use of talc-dusted surgical gloves to</p> <p>15 any sort of cancer?</p> <p>16 MR. ROTMAN: Objection.</p> <p>17 MS. AHERN: What's the objection?</p> <p>18 MR. ROTMAN: Your question was --</p> <p>19 MS. AHERN: I'm reading it.</p> <p>20 MR. ROTMAN: -- why are you so certain.</p> <p>21 MS. AHERN: Well, I just told you we're</p> <p>22 going back to this question.</p> <p>23 MR. ROTMAN: Okay. So you're asking --</p> <p>24 you're not saying that she didn't -- you're not</p> <p>25 repeating your former question?</p>	<p>1 get to the ovary and we know that talc can cause</p> <p>2 chronic inflammation.</p> <p>3 Q. Doctor, first question about your</p> <p>4 answer is: What makes you think that cosmetic</p> <p>5 talc used in Johnson &amp; Johnson baby powder is not</p> <p>6 pharmaceutical-grade talc?</p> <p>7 A. I'm talking about the product, the</p> <p>8 ultimate product.</p> <p>9 Q. Johnson's baby powder; correct?</p> <p>10 A. Whatever is in the bottle.</p> <p>11 Q. You're saying that's not</p> <p>12 pharmaceutical-grade talc?</p> <p>13 A. Whatever is in the bottle.</p> <p>14 Q. Okay.</p> <p>15 A. So --</p> <p>16 Q. What is your -- what is your</p> <p>17 understanding of what pharmaceutical-grade talc</p> <p>18 is and how is that different from what's in</p> <p>19 Johnson's baby powder?</p> <p>20 A. So I didn't opine on the constituents</p> <p>21 of the talcum powder that -- the baby product --</p> <p>22 talcum powder products, the Johnson &amp; Johnson. I</p> <p>23 saw evidence as to what's in the talcum powder</p> <p>24 products, but I didn't do my own analysis as to</p> <p>25 what is in the talcum powder products.</p>

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<p>1 But pharmaceutical-grade talc, if we're 2 talking about talc that's used in pleurodesis, 3 for example, is going to be different than talcum 4 powder products in the bottle -- 5 Q. Okay. 6 A. -- cosmetic talcum powder products. 7 Q. So how is it different? 8 A. So, again, I didn't do my own analysis 9 as to what is in the talcum powder product, but 10 that's what I am -- that's what my general 11 causation opinion is on, is the talcum powder 12 product in the bottle, that regular perineal use 13 of that causes ovarian cancer. 14 Q. My question to you is: What do you 15 understand the difference between the talcum 16 powder products and pharmaceutical-grade talc -- 17 MR. ROTMAN: Objection. 18 Q. -- to be? 19 A. So I've seen evidence that in talcum 20 powder products, there are heavy metals. There 21 are fragrances that are added to the talcum 22 powder product that, in talc used for 23 pleurodesis, they wouldn't be adding fragrances 24 to that type of talc. 25 Q. Would -- you're not saying that talcum</p>	<p>1 A. Well, I think I've answered, like, to 2 me, it doesn't -- it doesn't really matter 3 what -- the difference between pharmaceutical 4 talc and talcum powder products; it's whatever is 5 in that talcum powder products -- product, 6 whatever is in the bottle that women are buying 7 off the shelf and applying to their perineum. 8 MR. KLATT: Objection. Nonresponsive. 9 MS. AHERN: Objection. Nonresponsive. 10 Q. My question was -- originally was: Do 11 you know of any literature that connects talc 12 dust of surgical gloves and any sort of cancer. 13 And then you said, "First of all, I think 14 we're talking about surgical glove talc, which is 15 a pharmaceutical-grade talc, which is different 16 from the talcum powder product that I'm opining 17 about." 18 So what I'm asking you is: What is 19 different about the talcum powder product that 20 you're -- 21 A. It's what I'm opining about. You know, 22 I haven't -- 23 Q. Right. 24 A. -- looked at the talc that's used for 25 pleurodesis, for example. It's what I'm</p>
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<p>1 powder products that are sold to consumers have 2 been altered to add heavy metals, are you? 3 A. Well, I've seen the report of 4 Dr. Crowley that looks at heavy metals and 5 fragrances in the talc, the baby product talc 6 powder that he examined. I did not do my own 7 analysis of that. 8 Q. Does pharmaceutical-grade talcum powder 9 also have associated metals and sometimes heavy 10 metals? 11 A. I'm not sure if I've seen data as to 12 what is specifically in pharmaceutical-grade 13 talcum powder, but, again, to me, what is 14 important is the ultimate product and what is in 15 that bottle. It can -- whether it's platy talc, 16 fibrous talc, asbestos, heavy metals, fragrance 17 metals. 18 I mean, to me -- you know, I've seen 19 evidence of those things in that product, but to 20 me, what I'm looking at is the final product when 21 it comes to causing ovarian cancer. 22 Q. So what is different about that final 23 product and pharmaceutical-grade talc? What 24 specific components have been added to that that 25 affect your opinions in this case?</p>	<p>1 separating out. 2 I've looked at the talcum powder product 3 that women use on their perineum, what they 4 bought off the shelf. I haven't looked at 5 pharmaceutical-grade -- let me correct that -- 6 pleurodesis talc, for example. I have not looked 7 at pleurodesis talc and ovarian cancer. I have 8 not looked at any literature specifically on 9 that. It's been the talcum powder products that 10 women are buying off the shelf and using on their 11 perineum. 12 Q. So if I told you that Johnson's baby 13 powder starts out as pharmaceutical-grade talc 14 and that, beyond that, fragrance is added, would 15 it be the fragrance that you're taking issue with 16 that you believe is causally associated with the 17 development of ovarian cancer? 18 A. Again, I -- it's whatever is in that 19 bottle. It could be platy talc, fibrous talc, 20 asbestos, heavy metals, fragrance. It -- to me, 21 it's the product, whatever the product is that 22 they are using. 23 Q. And you have done a biologic 24 plausibility analysis for fragrances, for metals, 25 for asbestos, for fibrous talc, and for platy</p>

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<p style="text-align: right;">Page 134</p> <p>1 talc --</p> <p>2 A. So --</p> <p>3 Q. -- each one of those constituents?</p> <p>4 A. So I have looked at evidence -- so</p> <p>5 Dr. Crowley's report, I mentioned. I've looked</p> <p>6 at Dr. Longo's report. I've looked at Hopkins</p> <p>7 and the Pier charts from their depositions. I'm</p> <p>8 aware of evidence that these heavy metals and</p> <p>9 fragrances and asbestos are in there.</p> <p>10 However, I haven't done -- what I know, I</p> <p>11 looked at the -- I've looked at some literature</p> <p>12 and I've looked at the IARC categorization of the</p> <p>13 heavy metals. I've looked at Dr. Crowley's</p> <p>14 report and I've done an extensive look at</p> <p>15 asbestos and ovarian cancer.</p> <p>16 But, ultimately, those are just pieces of</p> <p>17 biological plausibility. What I'm mainly -- what</p> <p>18 I am opining about is the ultimate product. And,</p> <p>19 again, it can be platy talc, it can be fibrous</p> <p>20 talc, it can be asbestos, it can be heavy metals.</p> <p>21 It's pieces of information that strengthen</p> <p>22 the plausibility. We know that asbestos causes</p> <p>23 ovarian cancer, that certain heavy metals are</p> <p>24 carcinogens, which the IARC categorized them as.</p> <p>25 So it's just -- it's just additional pieces of</p>	<p style="text-align: right;">Page 136</p> <p>1 consistency piece of it.</p> <p>2 Q. Can I ask you -- you can go through all</p> <p>3 of it if you want, but would you rather break it</p> <p>4 down piece by piece?</p> <p>5 MR. ROTMAN: She should answer your</p> <p>6 question.</p> <p>7 MS. AHERN: I'm not sure she's</p> <p>8 answering my question. My question was: How do</p> <p>9 you come up with causation when you don't know</p> <p>10 what the exposure is?</p> <p>11 MR. ROTMAN: I think she's answering</p> <p>12 the question.</p> <p>13 MR. TISI: That wasn't the question.</p> <p>14 The question was: Do you need to know the agent?</p> <p>15 And she said the agent is the product.</p> <p>16 BY MS. AHERN:</p> <p>17 Q. The agent is everything in it?</p> <p>18 A. Yes, the agent is whatever is in that</p> <p>19 talcum powder product.</p> <p>20 Q. So are you basing, then, your causation</p> <p>21 conclusions on the epidemiologic literature</p> <p>22 alone?</p> <p>23 A. The epidemiologic literature is very</p> <p>24 comp- --</p> <p>25 MR. ROTMAN: She was not done with her</p>
<p style="text-align: right;">Page 135</p> <p>1 information that strengthen the biological</p> <p>2 plausibility arm of it.</p> <p>3 Q. Doctor, how do you arrive at a</p> <p>4 causation conclusion without a well-defined agent</p> <p>5 of exposure?</p> <p>6 MR. ROTMAN: Objection.</p> <p>7 Q. Do you understand what I'm asking you?</p> <p>8 How do you arrive at your causation and</p> <p>9 conclusion when you're not sure what it is about</p> <p>10 the talcum powder products that's actually</p> <p>11 biologically relevant?</p> <p>12 A. Well, I think -- well, strike that.</p> <p>13 The epi studies are looking at the product</p> <p>14 that the women are using. So that is the agent.</p> <p>15 It's the -- it's the total product. That is the</p> <p>16 agent.</p> <p>17 So when you're looking through -- let me</p> <p>18 just -- so let's keep in mind that we're looking</p> <p>19 at that product.</p> <p>20 And then if you go through my Bradford Hill</p> <p>21 analysis, you look at strength of association.</p> <p>22 And, overall, there's a consistent relative risk</p> <p>23 that's between 1 and 2. I would say it's, across</p> <p>24 studies, averaging 1.3 to 1.4 relative risk, and</p> <p>25 that's consistent across studies. That's the</p>	<p style="text-align: right;">Page 137</p> <p>1 earlier answer. Now you've gone two more beyond</p> <p>2 it.</p> <p>3 MS. AHERN: She's answering. Why don't</p> <p>4 you let her answer. If she wants to go back, she</p> <p>5 can.</p> <p>6 MR. ROTMAN: No, I want her to go back.</p> <p>7 She was -- she was in the middle of going through</p> <p>8 her Bradford Hill to answer your earlier question</p> <p>9 and you cut her off. So she had covered strength</p> <p>10 of association.</p> <p>11 BY MS. AHERN:</p> <p>12 Q. Doctor, you can answer the question the</p> <p>13 way you want to answer the question.</p> <p>14 MR. ROTMAN: Now there's no question in</p> <p>15 front of her.</p> <p>16 MS. AHERN: Well, because you</p> <p>17 interrupted it.</p> <p>18 MR. ROTMAN: Let's go back to what the</p> <p>19 question was before you cut her off. "Do you</p> <p>20 understand what I'm asking you? How do you</p> <p>21 arrive at your causation and conclusion when</p> <p>22 you're not sure what it is about the talcum</p> <p>23 powder products that actually biologically --</p> <p>24 that are biologically relevant?"</p> <p>25 And then you gave -- then you started</p>

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<p>1 an answer about the epi studies are looking at</p> <p>2 the product that the women are using, and you</p> <p>3 were talking about strength of association and</p> <p>4 then you said, "And that's consistent across</p> <p>5 studies. That's the consistency piece of it,"</p> <p>6 and then you were interrupted.</p> <p>7 So were you done with your answer to</p> <p>8 that earlier question?</p> <p>9 THE WITNESS: I can continue, because I</p> <p>10 think it's important.</p> <p>11 I mean, I was -- my general causation</p> <p>12 opinion, the methodology I used was to answer the</p> <p>13 question: Does perineal application of talcum</p> <p>14 powder products, the, you know, baby powder</p> <p>15 product that you buy off the shelf, does that</p> <p>16 cause ovarian cancer? So it's whatever is in</p> <p>17 that bottle.</p> <p>18 So with the methodology that I used,</p> <p>19 looking at the epi data, but also considering the</p> <p>20 Bradford Hill criteria -- which, you know,</p> <p>21 looking for specificity is another one. So most</p> <p>22 of the studies showed a stronger -- a strong</p> <p>23 association with serous ovarian cancer, but it</p> <p>24 was basically associated with epithelial ovarian</p> <p>25 cancer, so all groups of epithelial ovarian</p>	<p>1 generally accepted knowledge of the disease in</p> <p>2 question.</p> <p>3 So we know that particles can reach the</p> <p>4 ovary. We know that talc can cause chronic</p> <p>5 inflammation. We know that chronic inflammation</p> <p>6 is associated with certain types of cancer. We</p> <p>7 know that certain types of ovarian cancer have</p> <p>8 shown association with chronic inflammatory</p> <p>9 conditions.</p> <p>10 So, again, going through all this is</p> <p>11 experiment and analogy, experiment with the</p> <p>12 animal studies and the in vitro studies. And</p> <p>13 analogy, I used the example of asbestos, because</p> <p>14 even though asbestos is -- you know, asbestos is</p> <p>15 chemically similar, you can have asbestos fibers</p> <p>16 and talc fibers, but it's a similar mineral</p> <p>17 chemically, and we know that that is a</p> <p>18 carcinogen. So that's part of the analogy.</p> <p>19 But, again, it's the whole picture. I</p> <p>20 mean, you look at the -- all of this data</p> <p>21 following my methodology and you apply the</p> <p>22 Bradford Hill criteria guidelines -- the Bradford</p> <p>23 Hill guidelines. And, looking at all that, my</p> <p>24 professional judgment is that the talcum powder</p> <p>25 products can cause ovarian cancer.</p>
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<p>1 cancer. It was pretty specific, the epi data,</p> <p>2 for that type of ovarian cancer.</p> <p>3 Temporality. If you look at that, I</p> <p>4 mean, the case-control studies are retrospective</p> <p>5 reviews, so we know that they were using talc</p> <p>6 before their diagnosis of ovarian cancer.</p> <p>7 Biological gradient. For those studies</p> <p>8 that looked at a biological gradient, there was</p> <p>9 an evident -- there was evidence of a</p> <p>10 dose-response, not all of the times statistically</p> <p>11 significant, but the trend -- you can see a trend</p> <p>12 of a dose-response across studies.</p> <p>13 And then we get into the plausibility</p> <p>14 piece, which you've been discussing mostly so far</p> <p>15 in this deposition, which has to do with the</p> <p>16 plausible mechanism of talcum powder -- what I'm</p> <p>17 thinking of, talcum powder products -- whatever</p> <p>18 is in that bottle was what I'm looking at --</p> <p>19 talcum powder products causing -- the</p> <p>20 plausibility of it causing a chronic inflammatory</p> <p>21 response, leading to ovarian cancer. We've been</p> <p>22 discussing that quite a bit today.</p> <p>23 And then coherence. So I can refer</p> <p>24 again to my report. Coherence, in this context,</p> <p>25 means coherence between epidemiologic and</p>	<p>1 Q. Okay. Are you done? I don't want to</p> <p>2 interrupt you.</p> <p>3 A. I think I answered the question.</p> <p>4 Q. Okay. One of the things, and I guess a</p> <p>5 major component of the talcum powder products,</p> <p>6 would be talc; correct?</p> <p>7 A. Presumably -- it's called talcum</p> <p>8 powder, so presumably, talc would be a</p> <p>9 constituent.</p> <p>10 Q. Do you know what percentage of talcum</p> <p>11 powder products is talc?</p> <p>12 A. Again, I did not do my own analysis as</p> <p>13 to how much talc was in that product.</p> <p>14 Q. Do you know whether any of the heavy</p> <p>15 metals that you looked at or were examined by</p> <p>16 other experts in this litigation, whether any of</p> <p>17 those are known carcinogens for the ovary?</p> <p>18 A. So it's another piece of information.</p> <p>19 There is not, to my knowledge -- looking at what</p> <p>20 the IARC looked at, there's not data right now on</p> <p>21 those heavy metals and ovarian cancer, but</p> <p>22 it's -- it's a -- it's a piece of the puzzle.</p> <p>23 It's a piece of information.</p> <p>24 The IARC has called some of them</p> <p>25 carcinogenic, some of them probably carcinogenic,</p>

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<p style="text-align: right;">Page 142</p> <p>1 so we know that they can cause cancer. And if  2 they're in the talcum powder products, then it's  3 just another piece to the puzzle of plausibility.  4 Q. Are you saying that the probably  5 carcinogenic category for IARC means that they  6 can cause cancer?  7 A. Well, we can look at what the IARC 2A  8 categorization -- category actually says, what  9 they break it down. But my understanding is  10 it's -- probably carcinogenic means it probably  11 causes cancer, more likely than not, probably  12 causes cancer.  13 Q. How many categories does IARC have?  14 A. They have four.  15 Q. What is the -- what is Category 1?  16 A. Carcinogenic.  17 Q. Known to be carcinogenic?  18 A. Mm-hmm.  19 Q. And then the next?  20 A. Probably carcinogenic.  21 Q. And then?  22 A. Possibly carcinogenic.  23 Q. And then?  24 A. I think it's unclassifiable. I have to  25 look. But I think it's uncertain, basically.</p>	<p style="text-align: right;">Page 144</p> <p>1 little too wide a net. I think science is always  2 evolving and there's always the possibility of an  3 unknown cause of a certain type of cancer.  4 MS. AHERN: Objection. Nonresponsive.  5 Q. My question was just: Can carcinogens  6 be organ specific?  7 A. And I feel like I answered that fairly.  8 Q. Do you know of carcinogens that are  9 organ specific?  10 A. I know -- for example, we know that H.  11 Pylori causes increased risk of gastric cancer,  12 but not oral or esophageal cancer.  13 We know that HPV infection can cause  14 cervical cancer, anal cancer, certain types of  15 squamous cell carcinomas of the oropharyngeal  16 system, but not, you know, of the endometrium,  17 for example.  18 So we know that certain things cause certain  19 cancers and aren't -- haven't been associated  20 with other types of cancers. But to cast that  21 wide a net, to say that a carcinogen is only  22 going to cause one type of cancer or this cancer  23 is caused only by this carcinogen, I think that's  24 too wide a net, because I feel like research is  25 constantly evolving. We're constantly learning</p>
<p style="text-align: right;">Page 143</p> <p>1 Q. And then what is the last?  2 A. And then known not to be carcinogenic.  3 Q. How many agents are in the known not to  4 be carcinogenic category?  5 A. Very, very few.  6 Q. One, right?  7 A. That's plausible. I haven't looked at  8 the list recently.  9 Q. So going back to the major component,  10 you don't know what percentage of talcum powder  11 products are actually talc?  12 MR. ROTMAN: Objection.  13 A. I have not done my own analysis as to  14 what the components are of that talcum powder --  15 of the talcum powder products.  16 Q. Do you agree that carcinogens can be  17 organ specific?  18 A. I will agree that certain tissues  19 respond to certain things differently.  20 Q. Do you agree that carcinogens can be  21 organ specific?  22 A. Certain tissues respond to certain  23 things differently. If you're casting that wide  24 a net to say that one specific carcinogen only  25 causes one type of cancer, I think that's a</p>	<p style="text-align: right;">Page 145</p> <p>1 of new causal factors in cancer.  2 Q. Do you think that dose is an important  3 consideration when you're looking at the  4 toxicologic effects of an agent on a tissue?  5 A. I think it is a piece of information.  6 I'm looking at my biological gradient portion of  7 my report, and I said in my report that it was an  8 important factor in my analysis because it does  9 add information to the overall causality.  10 Q. Are there agents that can be toxic at  11 certain levels and not toxic at other levels?  12 A. There are certainly agents that are  13 more toxic with increased exposure and increased  14 duration. We don't know all of the thresholds  15 for carcinogenicity of all carcinogens.  16 Q. As part of the biologic plausibility  17 analysis that you would do on a particular agent,  18 would that take into consideration the relative  19 levels of exposure that a person would have to  20 that agent?  21 A. Well, dose-response -- I -- I'm taking  22 it -- your question -- can you rephrase the  23 question? I'm sorry. I just want to make sure  24 I'm answering it accurately.  25 Q. To determine whether it's biologically</p>

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<p>1 plausible for a particular agent to cause a 2 particular harm, would you need to be able to 3 characterize the dose of that agent that is 4 required to elicit the effect that you're looking 5 for?</p> <p>6 A. I think it's a piece of the 7 information -- a piece of information, but you're 8 not always going to be able to determine a 9 dose-response. It's going to depend on the 10 carcinogen, the agent, the routes of exposure. 11 You're just not always going to have that data, 12 unfortunately. It would be nice to have, but 13 you're not always going to have it, and you don't 14 necessarily have to have it to come to 15 plausibility.</p> <p>16 Q. And do you have well-characterized 17 levels of exposure to the ovaries for women who 18 are using talc perineally?</p> <p>19 MR. ROTMAN: Objection.</p> <p>20 A. So some of the -- we're never really 21 going to be able to figure out what an actual -- 22 to characterize what an actual dose -- dose of 23 talcum powder product of what -- of a talcum 24 powder product in a particular use. We don't 25 know how much a woman is putting on her hand to</p>	<p>1 and ovarian cancer. I certainly saw some of the 2 data about talc migration and cornstarch on 3 surgical gloves migration, but I didn't 4 specifically -- I don't know if -- I don't even 5 know if that study has really been done.</p> <p>6 Q. Did you consider the publications on 7 talc responses -- or, excuse me, did you consider 8 the publications on granulomatous reactions to 9 talc from surgical gloves to be relevant to your 10 biologic plausibility analysis?</p> <p>11 A. It's a piece of information that 12 talc -- now, again, surgical glove talc, for me, 13 is different than the talcum powder products.</p> <p>14 You know, my general causation opinion -- I 15 just want to be clear -- is about, you know, 16 talcum powder products, not the talc used in 17 pleurodesis, not talc on surgical gloves.</p> <p>18 Having said that, I think it's an important 19 piece of information to know that talc on 20 surgical gloves can cause a granulomatous 21 reaction, because that is further evidence for 22 plausibility that talcum powder products -- 23 they're called talcum powder products, so, again, 24 it's sort of an assumption. It doesn't really 25 matter to me what's in there, but my assumption</p>
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<p>1 place into the perineum. We don't know how much 2 of that product is getting to the ovary. We know 3 that it can get to the ovary because we've seen 4 talc in the ovary. But where -- it's extremely 5 difficult in this type of situation, when women 6 use the product differently, to know what the 7 dose -- what a single dose is.</p> <p>8 Now, if you're talking long-term, frequent 9 use of talcum powder products, of course, the 10 exposure is going to be greater than a single use 11 of that product.</p> <p>12 But are we ever going to know what one dose 13 of talcum powder product is? I don't think we're 14 going to be able to say that and how much of one 15 dose reaches the ovary.</p> <p>16 But, certainly, again, with -- over time, 17 increased frequency and duration, it's -- you 18 know, more of that product is going to reach the 19 ovary.</p> <p>20 Q. So going back to the discussion we had 21 earlier about surgical glove talc, do you know of 22 any literature that links exposure to talcum 23 powder -- pharmaceutical-grade talcum powder from 24 surgical gloves to any kind of cancer?</p> <p>25 A. I did not opine on surgical glove talc</p>	<p>1 is that whatever -- the talc or whatever is in 2 that product is causing the -- a chronic 3 inflammation. And so it's part -- it's a piece 4 of evidence for the plausibility.</p> <p>5 Q. So are you not aware of any studies, 6 based on the review that you did conduct, that 7 link surgical glove talcum powder with the 8 development of any cancer?</p> <p>9 MR. ROTMAN: Objection.</p> <p>10 A. So I'm not sure how you could do that. 11 If you're looking at patients who -- I think that 12 would be a very difficult study to design.</p> <p>13 If you're looking at women -- if you're 14 doing a case-control study -- I'm just 15 thinking -- and you're looking at patients who 16 have been diagnosed with ovarian cancer who have, 17 at any time, had surgery during the time period 18 that talc was used on surgical gloves, I think 19 that would be a difficult study.</p> <p>20 Q. My question to you was --</p> <p>21 MR. KLATT: Objection. Nonresponsive.</p> <p>22 Q. My question to you was: Are you aware 23 of any studies or literature that link 24 talc-dusted surgical gloves to the development of 25 any kind of cancer?</p>

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<p style="text-align: right;">Page 150</p> <p>1 MR. ROTMAN: Objection.  2 THE WITNESS: My thing is not --  3 MR. ROTMAN: There's a button you can  4 push.  5 THE WITNESS: Oh, "follow."  6 MR. ROTMAN: Do you see the button  7 that's flashing on the right-hand --  8 THE WITNESS: Yeah.  9 MR. ROTMAN: -- side? If you hit that,  10 it should go to the bottom.  11 THE WITNESS: Okay. I see. Yup.  12 MS. AHERN: And I'll withdraw that,  13 because there's -- the question asked first was,  14 I think, better. I slightly modified it on  15 accident.  16 BY MS. AHERN:  17 Q. Are you aware of any studies, based on  18 your review, that link surgical glove talcum  19 powder with the development of any kind of  20 cancer?  21 And, Doctor, to be clear, I'm only  22 interested in whether you know of a study, not  23 whether one could be conducted.  24 A. Off the top of my head, it's possible  25 that one exists, but I can't come up with one off</p>	<p style="text-align: right;">Page 152</p> <p>1 could be helpful information to my general  2 causation opinion. So it's possible that I did.  3 Q. Is it in your report or cited in any of  4 your reference lists?  5 A. Again, I can look through my whole  6 reference list. It's the same answer. Off the  7 top of my head, I don't know the answer to that.  8 Q. Do you know of any studies or any data  9 that link foreign-body granulomas to the  10 development of any kind of cancer?  11 A. Well, we know that asbestos can cause a  12 granulomatous reaction and asbestos is certainly  13 associated with mesothelioma and lung cancer.  14 Q. Are there other biologic properties of  15 asbestos that contribute to its carcinogenicity?  16 A. It can provoke a reactive oxygen  17 species inflammatory response.  18 Q. Can it disrupt DNA?  19 A. It can based on that mechanism, yes.  20 Q. Have you seen any studies or data  21 suggesting that talcum powder can do those  22 things?  23 A. I've seen studies that show that talcum  24 powder can increase production of reactive oxygen  25 species and can change gene expression in</p>
<p style="text-align: right;">Page 151</p> <p>1 the top of my head.  2 Q. Do you know of any data linking  3 surgical glove talcum powder with the development  4 of any cancer?  5 MR. ROTMAN: Objection.  6 A. It would be my same answer.  7 Q. That you don't know, but there might  8 be?  9 A. Sitting here right now, I can't come up  10 with a specific study that evaluated ovarian  11 cancer patients who have had surgery with talcum  12 powder gloves.  13 Q. Any cancer. Not ovarian cancer, any  14 cancer.  15 A. Similar. Sitting here right now, I  16 cannot think of one off the top of my head.  17 Q. And wouldn't that have been something  18 you think you would have picked up in your  19 review?  20 A. It's possible that I did. I just said  21 I can't think of it off the top of my head. It's  22 possible that I did at some point.  23 But my -- and, again, I tried to make every  24 effort to be able to identify studies and  25 literature and evidence that were relevant or</p>	<p style="text-align: right;">Page 153</p> <p>1 mesothelial cells. So, yes, I mean -- let me go  2 back to your question.  3 So I would say, yes, there are studies that  4 show talc can cause the production of reactive  5 oxygen species and reactive nitrogen species,  6 which can disrupt DNA, similar to asbestos.  7 Q. How do reactive oxygen and nitrogen  8 species disrupt DNA similar to asbestos?  9 A. Well, it's the reactive oxygen species  10 -- it's part of this feedback loop with -- what's  11 the word I'm looking for? -- tumor factors like  12 COX and TNF alpha. It's related to those types  13 of expressions and an inflammatory response.  14 Q. Are you relying on cell studies?  15 MR. ROTMAN: Objection.  16 A. I have looked at cell studies. The  17 Buz'Zard study is one, and I know Saed has done a  18 lot with myeloperoxidase and ovarian cells. He  19 recently came out with a paper.  20 So it's, again, a piece of information  21 towards the plausibility arm of my general  22 causation opinion.  23 Q. Have you seen any studies in animals or  24 in humans that have linked the specific enzymes  25 that Dr. Saed has evaluated in cell studies to</p>

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<p style="text-align: right;">Page 154</p> <p>1 the development of ovarian cancer?</p> <p>2 A. So there have been some studies that</p> <p>3 have looked at anti-inflammatory drugs, aspirin</p> <p>4 and NSAIDs in particular.</p> <p>5 The data on NSAIDs has been less consistent,</p> <p>6 but the data on aspirin has been consistent, in</p> <p>7 that it lowers the risk of ovarian cancer with</p> <p>8 regular aspirin use.</p> <p>9 And aspirin, one of the mechanisms of action</p> <p>10 is on the cyclooxygenase expression, which is</p> <p>11 similar to the cyclooxygenase expression seen in</p> <p>12 some of the in vitro studies.</p> <p>13 Q. So my question was: Have you seen any</p> <p>14 studies in animals or in humans that have linked</p> <p>15 specific enzymes that Dr. Saed has evaluated in</p> <p>16 his cell studies to the development of ovarian</p> <p>17 cancer?</p> <p>18 MR. ROTMAN: Objection.</p> <p>19 Q. Are you relying, then, on epidemiologic</p> <p>20 studies looking at NSAID and aspirin use?</p> <p>21 MR. ROTMAN: Objection.</p> <p>22 A. I'm saying that the NSAID and aspirin</p> <p>23 use is another piece of information that -- as to</p> <p>24 plausibility, mechanism -- and mechanism of</p> <p>25 regulation of pathways that can result in</p>	<p style="text-align: right;">Page 156</p> <p>1 get it.</p> <p>2 THE WITNESS: Oh, I'm sorry.</p> <p>3 A. "Ovarian cancer may be analogous,</p> <p>4 therefore, to plural mesothelioma, which has been</p> <p>5 shown to be caused by asbestos, a chemical</p> <p>6 similar to talc."</p> <p>7 Q. Is that the complete passage that</p> <p>8 you're looking at?</p> <p>9 A. I believe that is why I had highlighted</p> <p>10 that one, yes.</p> <p>11 Q. You'd agree that this version of</p> <p>12 Blaustein's textbook was published in 1994?</p> <p>13 A. Yes, I am aware.</p> <p>14 Q. Would you agree that a number of the</p> <p>15 risk factors that have been identified here,</p> <p>16 there have been additional studies published on?</p> <p>17 A. Yes.</p> <p>18 Q. Would you agree that alcohol is a known</p> <p>19 risk factor these days for ovarian cancer?</p> <p>20 A. I don't think that's been borne out to</p> <p>21 be the case. But with talc, there's continued to</p> <p>22 be several case controls and meta-analyses which</p> <p>23 have continued to be consistent with the</p> <p>24 increased risk of ovarian cancer cited in the</p> <p>25 studies that were cited here, which I didn't</p>
<p style="text-align: right;">Page 155</p> <p>1 reactive oxygen species and cause an inflammatory</p> <p>2 response.</p> <p>3 MR. KLATT: Objection. Nonresponsive.</p> <p>4 MS. AHERN: Same.</p> <p>5 Q. Let's go back to that. We'll finish up</p> <p>6 this Exhibit 11.</p> <p>7 What was the next page, if any, the last</p> <p>8 page in your photocopy?</p> <p>9 A. Okay. So this is Page 1216 of the</p> <p>10 fourth edition, if I am correct. Give me one</p> <p>11 second while I find it.</p> <p>12 Okay. So the reason why Page 1216 is there</p> <p>13 is because it starts the section on ovarian</p> <p>14 cancer, which then continues on to Page 1217.</p> <p>15 And it says -- the last paragraph on Page 1217</p> <p>16 says, "Other suggested factors affecting ovarian</p> <p>17 cancer risk include talc exposure, a history of</p> <p>18 mumps infection, and alcohol consumption. Talc</p> <p>19 exposure, which has been related to an excess</p> <p>20 risk of ovarian cancer in a number of</p> <p>21 case-control studies, is of interest biologically</p> <p>22 in that ovarian cancer is thought to arise from</p> <p>23 the mesothelium that lines the peritoneal</p> <p>24 cavity."</p> <p>25 MR. ROTMAN: Slow it down so she can</p>	<p style="text-align: right;">Page 157</p> <p>1 actually Xerox. You have the book, so --</p> <p>2 Yes, I agree this was 1994, but taken into</p> <p>3 context of the subsequent studies and literature</p> <p>4 looking at talc and ovarian cancer, I think it's</p> <p>5 still relevant.</p> <p>6 Q. Have there been a number of updates and</p> <p>7 changes to the classification of tumors since</p> <p>8 1994?</p> <p>9 A. Since 1994, sort of semantically. We</p> <p>10 still have the same subtypes of ovarian cancer.</p> <p>11 There's been a new categorization. We talked</p> <p>12 about the Type 1 and Type 2 ovarian cancers.</p> <p>13 So not a complete overhaul in</p> <p>14 categorization; I think just different ways to</p> <p>15 category the same entities, let's --</p> <p>16 Q. Has the --</p> <p>17 A. -- put it that way.</p> <p>18 Q. Sorry.</p> <p>19 Has the understanding of the origin of</p> <p>20 ovarian tumors evolved significantly since 1994?</p> <p>21 A. So this mentions -- we talked about</p> <p>22 this a little bit earlier -- this does mention</p> <p>23 that at this time, in 1994, there was thought</p> <p>24 that ovarian cancer might arise from the</p> <p>25 mesothelium. So the ovary is covered by a layer</p>

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<p>1 of mesothelium. That's the outer layer. And so 2 in 1994, that was still, I would say -- this is 3 before my residency, a little before my time -- 4 that that was the most common thought, that 5 that's where the ovarian cancer -- cancers are 6 arising from. Now, since then we've discussed 7 some of the other more recent findings of the 8 etiology.</p> <p>9 But, anyway, I just -- I had read this a 10 couple of days ago and, you know, it was -- it 11 was a reference that I think is still relevant 12 because of the -- the subsequent case controls 13 and meta-analyses that were done since then that 14 I think still make it relevant, although, again, 15 I -- we're not -- we're still not absolutely sure 16 where all of these ovarian epithelial tumors are 17 arising from. But we have a little more evidence 18 than we did in 1994.</p> <p>19 Q. And in 1994, the first prospective 20 cohort study had not yet been published; correct?</p> <p>21 A. I believe that is correct.</p> <p>22 Q. So we would be -- these numbers here 23 in -- that are discussed for talc exposure would 24 be, essentially, just the retrospective case 25 controls that had been published up to that point</p>	<p>1 page just because it was a continuation of that. 2 So, yes, I think we're done with the fourth 3 edition.</p> <p>4 Sorry. I'm starting to talk fast because 5 I'm excited for lunch.</p> <p>6 MS. AHERN: We can take a break for 7 lunch, then.</p> <p>8 THE VIDEOGRAPHER: Here ends Media 3. 9 Off the record, 1:05 p.m. 10 (Lunch recess was taken.) 11 ("Blaustein's Pathology of the 12 Female Genital Tract," Fifth Edition, 13 marked Exhibit 12.) 14 (Excerpt of Blaustein's 15 Pathology of the Female Genital Tract," 16 Fifth Edition marked Exhibit 13.) 17 THE VIDEOGRAPHER: Here begins Media 18 No. 4 in today's deposition of Sarah Kane, M.D. 19 Back on the record, 1:45 p.m. 20 BY MS. AHERN: 21 Q. Okay. Hi, Dr. Kane. 22 A. Hello. 23 Q. I'm looking here at Blaustein's 24 Pathology of the Female Genital Tract, Fifth 25 Edition, which you brought with you here today.</p>
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<p>1 or the specific ones --</p> <p>2 A. Yeah. You have the reference list of 3 the reference numbers 47, 69, 70, and 182.</p> <p>4 Q. Cramer? You said 59?</p> <p>5 A. 69.</p> <p>6 Q. Harlow, 92.</p> <p>7 A. 70.</p> <p>8 Q. 70. Hartge.</p> <p>9 And 83.</p> <p>10 A. And 182.</p> <p>11 Q. And Whittemore, 1988.</p> <p>12 A. So, yes, that was before. They only 13 looked up until 1988.</p> <p>14 Q. Okay.</p> <p>15 MR. ROTMAN: Hunter, a good time to 16 take our lunch break? It's been an hour since 17 our last -- since we started.</p> <p>18 MS. AHERN: Sure. I'm sure people 19 could use a bio break too.</p> <p>20 Q. Are these the only pages that you 21 photocopied from this book -- or in -- sorry. 22 Let me rephrase that.</p> <p>23 Have we finished with the photocopy of 24 Exhibit 11 or are there more pages?</p> <p>25 A. I think -- I think I Xeroxed this last</p>	<p>1 I marked it as Exhibit 12 to your deposition. 2 You can have it back.</p> <p>3 A. Okay.</p> <p>4 Q. Thank you. And inside, you brought 5 with you a photocopy of the cover page and also 6 Page 629. I'll hand that back to you. I think 7 there's only one copy. I've marked that as 8 Exhibit 13.</p> <p>9 A. Oh, okay.</p> <p>10 Q. Here you go.</p> <p>11 A. Okay.</p> <p>12 MR. TISI: What was the page? I'm 13 sorry.</p> <p>14 THE WITNESS: 629. Do you want the 15 textbook back?</p> <p>16 Q. Whichever one you'd rather actually 17 pass back to me. Thank you.</p> <p>18 Can you tell us, on Page 629, what 19 information you thought was relevant to your 20 review of the talc issue?</p> <p>21 A. Yes. I believe this is under "Foreign 22 Body." So this is diseases of the fallopian 23 tube. So under "Foreign Body" -- hold on one 24 second. Okay. It says, "Foreign material may be 25 introduced into the tube in the course of</p>

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<p style="text-align: right;">Page 162</p> <p>1   gynecologic investigation, especially 2   hysteroscopic -- I can't say the word, 3   hysterosalpingo -- anyway, HPG, lubricant jelly, 4   mineral oil and starch and talc powder may cause 5   a lipoid or granulomatous salpingitis. An 6   intense phagocytic reaction to introduce lipid 7   material causes" -- 8       THE COURT REPORTER: Excuse me. 9       A. Sorry. I think that's basically the -- 10   that is the end. 11       No. At the very end of the page, it says, 12   "Talc may cause mucosal or serosal granulomas. 13   Examination of all granulomas or foreign body 14   reactions under polarized light is useful in the 15   recognition of these processes. Other disease 16   processes in the tube such as leprosy or 17   amyloidosis are so infrequent that they are of 18   little clinical or pathologic significance." 19       Q. How does that information inform your 20   opinions today? 21       A. So it's just another -- again, similar 22   to the other things that we reviewed in the other 23   edition, just another piece of evidence that talc 24   causes mucosal and serosal granulomas, and 25   they're talking about the fallopian tube in this</p>	<p style="text-align: right;">Page 164</p> <p>1   experimental studies or animal studies 2   linking talc foreign-body responses to 3   development of cancer? 4       A. From what I can recall in those 5   textbooks, I don't think they went into any more 6   detail than what I've read for you. 7       Q. Okay. What else did you bring with you 8   today? Anything that we haven't covered other 9   than the boxes behind me? 10       A. Correct. I don't think so. Mr. Rotman 11   brought a copy of my report, but that is all. 12   This -- let me look. 13       All of these have been marked already. 14   Yeah. 15       Q. All right. Doctor, you've got a copy, 16   but I'm going to hand you another one. I've 17   marked as Exhibit 14 a copy of your expert report 18   dated November 15, 2018. 19       (Rule 26 Expert Report of Sarah 20   E. Kane, M.D. marked Exhibit 14.) 21       Q. Can you review Exhibit 14 and tell us 22   if this is indeed your expert report dated 23   November 15, 2018? 24       A. Yes. This appears to be my report. 25       Q. And you brought with you earlier an</p>
<p style="text-align: right;">Page 163</p> <p>1   chapter. 2       MR. KLATT: Can I interrupt? 3       (Discussion off the record.) 4       MR. LOCKE: I'm on right now. Thanks, 5   Mike. 6   BY MS. AHERN: 7       Q. And, Doctor, did you review any other 8   sections of Exhibit 12, Blaustein, Fifth Edition? 9       A. I believe I did. I think in this 10   edition, from what I recall, that was the -- the 11   reference was in the fallopian tube. 12       Q. Is that what we just discussed on 13   Page 629? 14       A. Yes. 629 was where talc was discussed 15   in the fallopian tube. 16       Q. Did you see any other information in 17   any of the Blaustein texts that we reviewed today 18   that suggests that foreign body granulomas caused 19   by talc have been associated with the development 20   of ovarian cancer? 21       A. Well, we saw mention of the 22   epidemiologic studies in the fourth edition that 23   we reviewed. 24       Q. So other than the epidemiology, is 25   there any reference to pathology studies or</p>	<p style="text-align: right;">Page 165</p> <p>1   updated copy of your CV; correct? 2       A. Yes, I did. 3       Q. Which we marked Exhibit 2. 4       (Document entitled "References 5   Cited and Other Material and Data 6   Considered" marked Exhibit 15.) 7   BY MS. AHERN: 8       Q. And Exhibit B to your report was 9   entitled "References Cited and Other Material and 10   Data Considered." I've marked that as Exhibit 15 11   to your deposition. 12       A. Okay. 13       Q. Okay. And Exhibit 15 isn't paginated 14   but consists of 11 pages. The first ten pages of 15   materials consist of 186 items identified by the 16   caption on the top of Page 1 as "Literature"; is 17   that correct? 18       A. I'm sorry. Are you talking about the 19   "References Cited and Other Material and Data 20   Considered," Exhibit 15? 21       Q. Yes. 22       A. Yes. There is a list of 186 literature 23   references. 24       Q. And the materials listed on Page 11 are 25   identified by a caption as "Other Sources" and</p>

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<p>1 include an additional 17 items; is that correct?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. So did you prepare Exhibit 15?</p> <p>4 A. Yes. I did.</p> <p>5 Q. Did you type this out yourself?</p> <p>6 A. I did. Yes.</p> <p>7 Q. Okay. And how did you go about pulling</p> <p>8 this together?</p> <p>9 A. I'm -- in what way?</p> <p>10 Q. Did you keep a running list of the</p> <p>11 citations as you went and then pull this all</p> <p>12 together at the end of your report?</p> <p>13 A. Yes. So what happened is this was my</p> <p>14 first medical expert witness report I have</p> <p>15 written. And you'll notice that -- let's see,</p> <p>16 all of the -- oh, I'm sorry. This doesn't</p> <p>17 include the January 4th list; right?</p> <p>18 Q. We'll get there.</p> <p>19 A. Okay. So that's what I kind of want to</p> <p>20 explain. What happened is, the reason why you</p> <p>21 had a January 4th list, is because I wrote</p> <p>22 this -- the accepted form for published</p> <p>23 literature is listing literature that you've</p> <p>24 actually cited within the body of your report,</p> <p>25 and so it was my misunderstanding. I was not</p>	<p>1 that you -- the list that you got yesterday is</p> <p>2 stuff that I had reviewed, I believe. I have to</p> <p>3 look at it.</p> <p>4 But my point is that list that you got</p> <p>5 yesterday was varied, and -- when I looked at it,</p> <p>6 and it was just an effort to be as complete as</p> <p>7 possible.</p> <p>8 Q. Okay. And just looking -- we'll get</p> <p>9 there, but just looking at Exhibit 15, which --</p> <p>10 the first ten pages, which are the references?</p> <p>11 A. Mm-hmm.</p> <p>12 Q. So do you define the references as the</p> <p>13 specific sources that you cited within the body</p> <p>14 of your report?</p> <p>15 A. These are sources that I cited within</p> <p>16 the body of my report.</p> <p>17 Q. And are these the sources that you rely</p> <p>18 on to support the opinions expressed in your</p> <p>19 report?</p> <p>20 A. So these are some of the references</p> <p>21 that I used. Again, I also had reviewed the</p> <p>22 subsequent -- the literature and the other data</p> <p>23 in the subsequent lists. So I would not say this</p> <p>24 is all-encompassing, but ultimately, with all the</p> <p>25 lists you have now, I'm hoping that that is</p>
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<p>1 aware at first that you guys were going to want a</p> <p>2 list of everything that I had reviewed.</p> <p>3 So what I tried to do is this, I think, was</p> <p>4 turned in at the same time, so Exhibit 15 was</p> <p>5 turned in at the same time as Exhibit 14, and it</p> <p>6 has the literature that was cited within the body</p> <p>7 of the report.</p> <p>8 And then when I realized I needed to get a</p> <p>9 list together of everything, as complete a list</p> <p>10 of everything that I thought I reviewed, I put</p> <p>11 together the January 4th list, which was -- I had</p> <p>12 to sort of recreate -- and I kept almost all of</p> <p>13 those -- all of this literature in different</p> <p>14 files.</p> <p>15 I had to do a little bit of recreation</p> <p>16 because, as I mentioned before, I lost a couple</p> <p>17 of hard drives during this whole process, which</p> <p>18 was not fun. But thankfully, I was -- I had</p> <p>19 backed up a lot of it.</p> <p>20 So I tried to be as complete as possible.</p> <p>21 It is possible that there are a few things I</p> <p>22 reviewed that did not make the list, which I</p> <p>23 think I realized on the list that you got</p> <p>24 yesterday there might have been a couple that I</p> <p>25 had reviewed before, but most of that literature</p>	<p>1 encompassing of at least all of the stuff that I</p> <p>2 considered. I wouldn't necessarily say "rely</p> <p>3 on," but at least everything that I considered.</p> <p>4 Q. Okay. And that was -- my next question</p> <p>5 was: Do you differentiate between the sources</p> <p>6 cited here as references and those that you just</p> <p>7 considered but weren't included as references?</p> <p>8 A. Not necessarily. These are the ones</p> <p>9 that ended up getting cited in the report. Now,</p> <p>10 there were different drafts, which at one point</p> <p>11 some of the other ones were cited, and there was</p> <p>12 a little bit of changing it around, which there's</p> <p>13 a couple -- I think there are a couple of</p> <p>14 typographical-type errors in a couple of the</p> <p>15 references because of that.</p> <p>16 But essentially, there isn't that much of a</p> <p>17 difference, I would say, except to say that this</p> <p>18 is the literature that I ended up specifically</p> <p>19 citing.</p> <p>20 But all of the literature that I looked at,</p> <p>21 I considered.</p> <p>22 Q. Would you say that all of the</p> <p>23 literature that you looked at, which would</p> <p>24 include your other sources here on Exhibit 15,</p> <p>25 your January 4, 2018, reference list, and the</p>

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<p>1 ones served yesterday, January 24th, would you 2 say that you relied on all of those materials? 3 A. No. Well, I at least reviewed those. 4 I would say that I considered them. I wouldn't 5 necessarily say that I relied upon them. 6 Q. And when you consider material, what 7 does that mean to you? 8 A. Well, you know, when I'm -- you can 9 look at my methodology, how I tried to cast as 10 wide a net as possible with the information that 11 I gathered in the information stage. So I wanted 12 to have as much data, as many literature 13 references, expert reports, whatever I could kind 14 of get my hands on that might be relevant to my 15 general causation report. 16 And then I'm reading through those, and 17 that's actually when I started my draft of the 18 report. It really started as sort of notes that 19 I took as I read the different literature 20 references, and I sort of built out from there. 21 Does that answer your question? 22 Q. I think probably so. 23 Did you collect -- did you identify all of 24 the materials in Exhibit 15 yourself, or were 25 some of these provided to you by the plaintiffs'</p>	<p>1 remember, I did my own literature search, read as 2 much as possible, started taking my own notes. 3 And then thought, as I was sort of forming my 4 opinion, thought, you know, it would be nice to 5 know what the defense is saying. And, of course, 6 I think at that point is when I asked, but I 7 don't remember specific timing. 8 Q. And did you specifically -- did you ask 9 for specific defense reports or specific defense 10 reports related to particular expertise? 11 A. If I recall -- I'm looking at this 12 list -- I believe the first request was a more 13 general request. 14 Q. When you say "more general," do you 15 mean for -- 16 A. Meaning -- 17 Q. -- for defense? 18 A. -- I didn't ask for specific names of 19 people. 20 Q. Ah. 21 A. I think at this point, I wasn't 22 necessarily aware of who would have been defense 23 experts. And so I don't remember exactly, but my 24 inclination is that I had asked for a more 25 general sort of representation.</p>
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<p>1 counsel? 2 A. The vast majority of them, I found 3 through my own literature search. Some of them 4 may have been supplied by the plaintiffs' 5 attorneys. A lot of those overlapped with what I 6 had already found; the exception, of course, 7 being documents on the other sources that I would 8 not have had access to on my own. 9 So I had asked for, and in forming my 10 opinion, my general causation opinion, I had 11 asked for defense expert reports so I could get a 12 sense of what the defense experts' opinions were, 13 just to get, you know, the other -- just to get 14 more information. 15 So that's -- so those were definitely given 16 to me by plaintiffs' attorneys. 17 Q. Do you remember, timewise, did you 18 review the defense expert reports and the 19 materials in the other sources earlier on to get 20 a sense of the issues in the litigation and then 21 do your literature search, or the other way 22 around? What was the timing? 23 A. I don't remember exactly. I don't 24 believe I read the -- I'm trying to think timing. 25 I think what I did is -- from what I</p>	<p>1 Q. And can you identify on here which of 2 the other sources are from defense experts? 3 A. Yes. I'll try my best. 4 The Michael Ober expert report was provided 5 by plaintiffs' counsel. The deposition of Alice 6 Blount was also provided by plaintiffs' counsel. 7 Both of the Chodosh, his report and his trial 8 testimony, was provided by plaintiffs' counsel. 9 Samuel Cohen was provided by plaintiffs' counsel. 10 And also -- also, let's see, the Cramer, I 11 wouldn't have access to the Cramer reports on the 12 Byrd and Jacqueline Fox. The expert report of 13 Michael Crowley was given to me. That, 14 obviously, is a plaintiffs' report that was 15 within a day or two of turning in my report. 16 That was very late in the process. 17 John Godleski, I might have asked for by 18 name. Of course, he's a plaintiffs' expert. 19 His, I may have asked for by name because of the 20 Cramer papers. 21 Q. Did you say Cramer was a plaintiff or 22 defense expert? 23 A. Cramer, I believe, was a plaintiff. 24 Q. I wasn't sure. You named him after the 25 defense experts. I'm sorry. I'm just going</p>

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<p style="text-align: right;">Page 174</p> <p>1 through the list. 2 MR. ROTMAN: The list is alphabetical, 3 so she's going down the list. 4 BY MS. AHERN: 5 Q. Yeah. My question was: Which ones are 6 the defense experts? 7 A. I'm sorry. 8 Q. If you're done, you're done. Are there 9 any other defense experts. 10 A. Well, the John Hopkins and Julie Pier, 11 those exhibits and depositions I got from 12 plaintiffs' counsel. 13 I believe that is it, looking at the list of 14 defense reports. 15 Q. Did you want to know what the defense 16 experts had to say about epidemiology? 17 A. I wanted -- yeah. I wanted as much 18 evidence as I could get, so -- 19 Q. Were you aware that the defendants had 20 designated epidemiologists in the litigation who 21 had given reports and testimony? 22 A. I don't know if I was aware 23 specifically of that. 24 Q. Were you aware that the defense had 25 designated a number of gynecologic pathologists</p>	<p style="text-align: right;">Page 176</p> <p>1 ones that I received. Yes. 2 Q. Is there anyone on this list that's -- 3 that specifically addresses gynecologic 4 pathology? 5 A. I think it's been a long time since I 6 read those reports, but I do remember some of 7 those reports speaking to -- your question was on 8 top. I'm just making sure. 9 Q. Sure. 10 A. Some -- so the gyn onc report 11 definitely went into some gynecologic pathology. 12 Gyn oncs are generally knowledgeable about gyn 13 pathology because we work pretty closely with 14 them. We often show our gyn pathology, for 15 example, at multiconferences, multidisciplinary 16 conferences. 17 So I vaguely remember a gyn onc one going 18 over some gyn path stuff, but my memory is vague 19 because I have not read these in probably over a 20 year. I don't know exactly. 21 Q. Would you be interested in what the 22 epidemiologists that had served reports and given 23 testimony in the litigation the last five years, 24 what they've said? 25 MR. ROTMAN: Objection.</p>
<p style="text-align: right;">Page 175</p> <p>1 who had given reports and testimony as well? 2 A. Again, I don't know if I was 3 specifically aware of that. No. 4 Q. Would you have, as a pathologist doing 5 an expert report on this litigation, would you 6 have been interested to know what the defense 7 pathologists had said? 8 A. Well, I will take any data that I can 9 get to try to see if it's relevant. I mean, so I 10 had asked for defense reports, and that's what I 11 got. 12 Q. These reports, these other sources, the 13 17 items here were in response to your request, 14 but they were chosen by the plaintiffs' counsel? 15 MR. ROTMAN: Objection. 16 A. I'm not sure how they were chosen or 17 how -- why -- all I know is that I asked for 18 reports, and this is what I received. 19 Q. And you specifically asked for defense 20 reports; right? 21 A. I did. 22 Q. And you got Michael Beer, who is an 23 oncologist; Lewis Chodosh, a cancer biologist; 24 and Sam Cohen, a toxicologist; correct? 25 A. That would appear, from the list, the</p>	<p style="text-align: right;">Page 177</p> <p>1 A. Again, I'll take whatever information 2 or data, you know, I can get that might be 3 relevant. 4 Q. And do you consider expert litigation 5 reports to be data? 6 A. Yes. I think it's data. 7 Q. Okay. Is it the kind of data you rely 8 on in your everyday practice as a pathologist? 9 A. I sort of view they're opinion reports. 10 They're opinion, general causation opinions, and 11 a couple of these are -- I can't remember. All 12 of these were general, I believe, from the 13 defense. 14 So they're professional opinion data, and I 15 would say that's similar to having a consultation 16 with a colleague or a peer. I mean, you know, in 17 my day-to-day practice, I'm certainly asking 18 opinions of colleagues and different specialties 19 or my own specialty, even. Those are 20 professional judgments, professional opinions, 21 looking at their knowledge of the literature or 22 data. 23 So I think it's a good analogy; looking at 24 general causation, professional opinions, is 25 similar to kind of getting a colleague's opinion.</p>

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<p>1 Q. But this is the first time you've 2 relied on litigation reports to inform your own 3 opinions; correct? 4 A. Well, again, I don't know if I would 5 use the word "rely." I certainly considered 6 them, you know. But, again, I think it's very 7 similar to asking a colleague in my daily 8 practice for an opinion on something. 9 Q. And, Doctor, looking at 186 references 10 that are cited in Exhibit 15. 11 Did you review each one of these carefully 12 and thoroughly? 13 A. I reviewed each one of them, some of 14 them probably more thoroughly than others, 15 depending on what I was looking for; but yes, I 16 reviewed all of them. 17 Q. And do you know whether or not the 18 boxes, the four boxes that are sitting behind me, 19 do those include these 186 references on 20 Exhibit 15? 21 MR. TISI: Let me see if I can help you 22 out. 23 MS. AHERN: Sure. Go ahead. 24 MR. TISI: My understanding is they do. 25 MS. AHERN: That's the 186?</p>	<p>1 But I don't believe I -- well, I might 2 have referenced the Longo. 3 BY MS. AHERN: 4 Q. Page 5. I think if you look at Page 5 5 of your report, you reference Dr. Blount -- 6 A. Yes. 7 Q. -- Dr. Crowley, Longo, Rigler, 8 Hopkins -- 9 A. Yes. 10 Q. -- Pier? 11 A. Yes. Looking back at the list, you're 12 absolutely correct. I did. 13 Q. Do you think, as you sit here, that 14 those are -- 15 MR. TISI: I can look at them if it 16 makes your life easier. I'm happy to do it. 17 But I do think -- Mike is back there 18 looking. I'm thinking that those are the actual, 19 relied-on referenced materials, not the materials 20 considered, which was a separate list. 21 MS. AHERN: That's the January 4th, and 22 we're going to get to that one. 23 MR. TISI: No. it's in the back of the 24 report. Maybe I'm wrong. 25 MS. AHERN: There are other sources,</p>
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<p>1 MR. TISI: That would be the references 2 in the report. It would not be, to my -- I 3 haven't cracked the boxes, so I can only assume 4 from past prologue that the information 5 considered is not in those boxes. They may be, 6 but the information relied on that is cited in 7 the report are. 8 MS. AHERN: Okay. So other sources 9 here that are not cited specifically, well, they 10 may be -- 11 MR. TISI: I don't know, for example -- 12 well, maybe we can open them up. But I don't 13 know, for example, if the expert reports and 14 depositions are in the -- in there. If they're 15 cited, then they're probably in there. If 16 they're not cited -- 17 THE WITNESS: I'm not sure because -- 18 I'm not sure I cited these in my report because 19 they weren't necessarily reliance. It was more 20 data. 21 But I thought at the time that I should 22 list what -- because these aren't publicly -- I 23 don't believe any of these are publicly 24 available, what is on this list, so I felt like I 25 should list them.</p>	<p>1 but she has apparently relied on them -- 2 MR. TISI: That's fine. 3 MS. AHERN: -- to some extent in 4 performing reviews about fragrances and asbestos. 5 BY MS. AHERN: 6 Q. Is that right, Doctor? 7 A. Dr. Crowley's report and Dr. Longo's 8 report, yes. I -- 9 Q. And what about Dr. Hopkins and Pier? 10 A. Yes. I don't believe I read their 11 entire depositions. I know I had seen the 12 exhibits from the depositions, and I think 13 part -- I listed it here, so I must have at some 14 point. 15 MS. AHERN: Okay. So let's put 15 over 16 here, and let's move on to the next one. 17 (Document entitled "Additional 18 Material Considered" marked Exhibit 16.) 19 BY MS. AHERN: 20 Q. Okay. Doctor, I'm handing you what's 21 been marked as Exhibit 16 to your deposition. 22 Can you take a look at Exhibit 16 and tell 23 us what that is? 24 A. Yes. So this is a combination. So 25 once I realized that I needed to give you all a</p>

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<p style="text-align: right;">Page 182</p> <p>1 list of -- as complete a list as I could -- I'm 2 not going to say this is a complete list -- and, 3 of course, you have another list that you just 4 got, but I tried to be as complete as I could in 5 recreating the literature and other reports that 6 I had considered. 7 So these are ones that, to my recollection, 8 I didn't specifically cite or were not 9 available -- I mean, obviously, I have some of 10 the plaintiffs' expert reports that weren't 11 available to me until after I had written and 12 submitted my report. So some of these were 13 available to me only after -- and the Health 14 Canada came out after my report. 15 So these are a combination of things I 16 reviewed subsequent to November 15th and stuff 17 that I had reviewed prior to that but had not 18 specifically cited and recreated the list. 19 Q. Okay. And just for the record, this 20 is -- Exhibit 16 is a four-page document. It's 21 not paginated, but it has 96 items identified as 22 "Additional Materials Considered," so -- served 23 on January 4, 2018. 24 Can you identify, as you look through these 25 items on Exhibit 16, which of those you reviewed</p>	<p style="text-align: right;">Page 184</p> <p>1 A. No. 2 Q. And are there some materials on 3 Exhibit 16 that were provided to you or 4 identified for you by the plaintiffs other 5 than -- and I'm not talking about the litigation 6 materials, but the articles? 7 A. Again, there might have been some that 8 overlapped with what I had already found. I'm 9 looking. 10 I believe the April 2014 FDA letter may -- 11 although that might have been available on the 12 internet. I might have come across that on my 13 own first. 14 No. I believe the vast majority of this 15 stuff was stuff that I -- other than those 16 reports was stuff that I had independently 17 already found. That's the only one that is 18 ringing a bell as a possibility, but I also seem 19 to remember finding it on the internet. 20 Q. Okay. And are any of these materials, 21 materials that you explicitly rely on or, excuse 22 me, are any of the materials on Exhibit 16 23 materials that you rely on to support your 24 opinions? 25 A. Again, it's all data that I considered.</p>
<p style="text-align: right;">Page 183</p> <p>1 prior to the submission of your report and which 2 ones you reviewed after? 3 A. I can do the best that I can. My 4 memory might be a little -- and I have to jog my 5 memory a little bit on some of them. 6 Clearly, the expert reports that were 7 dated -- the plaintiff expert reports that were 8 dated after my report, I had not seen -- 9 Q. Mm-hmm. 10 A. -- prior. 11 And, again, the Health Canada came out 12 afterwards, so that was not available when I 13 submitted my report. The majority of the rest of 14 the literature, I had read prior to submitting my 15 report. 16 Q. Okay. Had you seen any draft reports 17 from any of the other experts designated by the 18 plaintiffs in this litigation? 19 A. Not before my report. I didn't see any 20 drafts. I only saw the final reports after my 21 report was submitted. 22 Q. Okay. Did you have an opportunity to 23 talk with any of the other experts that were 24 designated by plaintiffs prior to your report 25 being submitted?</p>	<p style="text-align: right;">Page 185</p> <p>1 I didn't specifically cite them, but there's 2 certainly pieces of information that helped me 3 come to my conclusion. 4 Q. And you prepared Exhibit 16, didn't 5 you? 6 A. Yes. 7 Q. And do you remember when you prepared 8 it? 9 A. Very shortly before you received it. 10 So it would have been -- you received it 11 January 4th? 12 Q. Mm-hmm. 13 A. I think I -- it was only -- I don't 14 remember exactly, but it wasn't very long before 15 that that I put it all together, after 16 recreating -- trying to recreate as best I could 17 the list of literature that I had reviewed. 18 Q. And did you carefully and completely 19 review all of the information in Exhibit 16? 20 A. Again, I reviewed all of it. Some of 21 it was more relevant than others, likely, so -- 22 but I reviewed all of them. 23 Q. Okay. Obviously, anything that you 24 received after your report is information you 25 would not have relied on to form your opinions in</p>

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<p style="text-align: right;">Page 186</p> <p>1 this case; correct?</p> <p>2 A. No. It's more information for my -- my</p> <p>3 opinion hasn't changed since I wrote my report.</p> <p>4 In fact, I know we've talked about Health Canada</p> <p>5 a little bit, but that was pretty interesting to</p> <p>6 see that report because their methodology was</p> <p>7 very similar to mine, and they did a Bradford</p> <p>8 Hill analysis, and they looked at a lot of the</p> <p>9 same literature and came to the same conclusion.</p> <p>10 So that definitely was supportive evidence,</p> <p>11 I think -- not I think; it is -- of my opinion.</p> <p>12 Q. And, Doctor, I only have one copy of</p> <p>13 this. It's "Additional Materials to Sarah Kane"</p> <p>14 that were served last night or yesterday</p> <p>15 afternoon, January 24th.</p> <p>16 (Document entitled "Additional</p> <p>17 Materials to Dr. Sarah Kane" marked Exhibit</p> <p>18 17.)</p> <p>19 BY MS. AHERN:</p> <p>20 Q. First of all, can you take a look at</p> <p>21 that?</p> <p>22 Have you seen it before?</p> <p>23 A. Yes. Yes. I have.</p> <p>24 Q. Did you prepare that?</p> <p>25 A. I did. I had listed -- there are a</p>	<p style="text-align: right;">Page 188</p> <p>1 I think that covers most of them.</p> <p>2 Q. What about the EFSA guidance on the use</p> <p>3 of weight of evidence?</p> <p>4 A. Oh, yeah. That, I think, I reviewed</p> <p>5 after I had submitted my report.</p> <p>6 Q. Did that form part of the basis of your</p> <p>7 opinions or your methodology?</p> <p>8 A. It was more of a -- it basically shows</p> <p>9 that the methodology that I used is very similar</p> <p>10 to evidence-based medicine that we would use on a</p> <p>11 daily basis. It kind of went through weight of</p> <p>12 evidence, and it was sort of helpful to see the</p> <p>13 similarity of the methodology that I used coming</p> <p>14 to my conclusion.</p> <p>15 Q. Was the methodology you used for</p> <p>16 preparing your opinions in this case and your</p> <p>17 report in this case taken directly from the EFSA</p> <p>18 guidance?</p> <p>19 A. No. I think I just -- I saw this EFSA</p> <p>20 guidance after writing my report.</p> <p>21 Q. Did you use any other sort of published</p> <p>22 methodology on weight of the evidence when you</p> <p>23 prepared your opinions?</p> <p>24 A. I used what we have been trained to</p> <p>25 use. I mean, it's evidence. It's an</p>
<p style="text-align: right;">Page 187</p> <p>1 couple of papers that I realize I had read</p> <p>2 previously and didn't -- I can tell you Purdie,</p> <p>3 1995, Keskin, 2009, I definitely reviewed while</p> <p>4 preparing my report, and somehow those got off</p> <p>5 the list.</p> <p>6 The other ones, Taher wasn't available. I'm</p> <p>7 trying to remember Gordon, if I had seen that.</p> <p>8 If I had seen that before I submitted a report,</p> <p>9 it was very late. It might have been after.</p> <p>10 The IARC heavy metals, I believe I actually</p> <p>11 cited that in my reference list, but I was trying</p> <p>12 to be -- it was one of these last-minute, trying</p> <p>13 to be as complete as possible, so that actually</p> <p>14 might be a repeat.</p> <p>15 The website, I had reviewed prior to turning</p> <p>16 in my report. And the Longo supplemental report,</p> <p>17 obviously, wasn't available until January. Same</p> <p>18 with the depositions. Those weren't available</p> <p>19 until after they were done.</p> <p>20 The Kurman defense report, I asked for</p> <p>21 recently when I realized that Kurman was a</p> <p>22 listed -- a named expert witness, which is also</p> <p>23 why I went through my copies of my old textbooks</p> <p>24 and my partner's old textbooks. So that, I asked</p> <p>25 for specifically.</p>	<p style="text-align: right;">Page 189</p> <p>1 evidence-based medicine model of methodology and</p> <p>2 coming to conclusions. So it's -- I tried to do</p> <p>3 as thorough as possible description of my</p> <p>4 methodology, which we can refer to in my report</p> <p>5 if you'd like.</p> <p>6 Q. What about the J&amp;J Science Day</p> <p>7 presentation?</p> <p>8 A. That --</p> <p>9 MR. ROTMAN: Objection. Is there a</p> <p>10 question?</p> <p>11 MS. AHERN: I'm about to get there if</p> <p>12 you'd let me finish my question.</p> <p>13 MR. ROTMAN: I thought you were.</p> <p>14 Sorry.</p> <p>15 MS. AHERN: You might just hold off.</p> <p>16 BY MS. AHERN:</p> <p>17 Q. What about the J&amp;J Science Day</p> <p>18 presentation? Is that something that you</p> <p>19 reviewed?</p> <p>20 A. I reviewed that very quickly, and I</p> <p>21 only received that maybe a week ago. It was very</p> <p>22 recently.</p> <p>23 Q. Did you request that information?</p> <p>24 A. I think, from what I remember, it was</p> <p>25 part of asking for more sort of defense side of</p>

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<p style="text-align: right;">Page 190</p> <p>1 the story; what, you know, your experts might 2 have been saying; what kind of -- you know, I was 3 trying to figure out how somebody who had looked 4 at the same body of evidence that I did can come 5 to a different conclusion, so it was part of sort 6 of that request. 7 I think I probably got it after I requested 8 Kurman's defense report from a prior litigation, 9 if memory serves me correctly. 10 Q. You would agree that a very large part, 11 not just volume, but a very large part of your 12 report and your opinions in this case are related 13 to the observational epidemiology on talc and 14 ovarian cancer; is that correct? 15 A. Well, I think that epidemiology 16 literature is extremely compelling. You have 17 30 case-control studies over different periods of 18 time in different populations that have come to 19 the same -- same ballpark relative risk, I would 20 say, 1.3 to 1.4. 21 Now, not all of those have been 22 statistically significant, but some of those 23 studies were smaller studies, and so that tends 24 to decrease the power of the study and your 25 confidence intervals will be wider.</p>	<p style="text-align: right;">Page 192</p> <p>1 is such a rare disease, and you're sort of, you 2 know, rolling the dice when you enroll patients 3 as to whether or not they're going to end up with 4 a disease at the end that you want to study. 5 So you're sort of -- and these cohorts are 6 also designed for multiple endpoints and multiple 7 diseases. They weren't just looking, most of 8 them -- I believe the sister -- well, the sister 9 study -- anyway, we can pull it out if I have to, 10 but my point is the cohort studies are designed 11 for multiple different things, especially the 12 Nurses' Health Study. 13 And so it's a difficult type of study to 14 design with a very rare disease. And I think 15 that's where the case-control studies are 16 important because you can start with the disease 17 and work backwards, and so you can have an easier 18 time getting cases. 19 Q. Did you find it interesting or odd that 20 you were provided with a number of defense expert 21 reports, but not a single one of them related to 22 the epidemiology specifically from an 23 epidemiologist? 24 A. Well, you know, again, I don't pretend 25 to know why I was sent what I was sent. I just</p>
<p style="text-align: right;">Page 191</p> <p>1 But I thought the epi data was really 2 compelling. And often in causation, the epi data 3 sort of leads the way in paving a path to 4 figuring out causation. 5 A perfect example is tobacco. You know, the 6 Surgeon General issued his report in the 1960s 7 about tobacco before they had any mechanism for 8 tobacco causing -- so that was a perfect example 9 of the epi data leading to causation. 10 So it's true, a lot of the studies looking 11 at talcum powder products and ovarian cancer are 12 epidemiology studies, but they're extremely 13 informative in that they are very consistent in 14 their findings. And, again, different authors, 15 different populations, different countries. 16 And there's also the cohort. So I went 17 through the cohort studies. The cohort studies, 18 some of them showed an association with serous 19 invasive carcinoma, but the cohort studies didn't 20 tend to find, other than that, a statistically 21 significant increased risk, although some of them 22 did find increased risk. 23 But we can talk about cohort studies versus 24 case-control studies if you want, but I think the 25 difficulty with cohort studies is ovarian cancer</p>	<p style="text-align: right;">Page 193</p> <p>1 know that I asked for reports, and I got what I 2 got. So I have no idea what the process was in 3 deciding what I received; if there was even a 4 decision. For all I know, it's just what they 5 had readily available. 6 Sorry. What is the question? 7 Q. Well, let me ask another question. 8 MR. ROTMAN: Let her finish the answer 9 because you can read -- she can go back and read 10 from the realtime what the question was and see 11 if she's done. 12 A. So I guess I don't know if there was 13 thinking -- what the thinking was or if there was 14 any. But also I can say that the epi data -- I 15 knew that by that point that the epi data was 16 consistent by the time I -- I think that was the 17 first literature that I was looking at, and so I 18 knew that it was consistent. 19 So it's -- anyway, I don't really -- I don't 20 know is the answer, the short answer. 21 The long answer, the short answer is I don't 22 know why I got what I did. I just did. 23 Q. Okay. And you've seen the designations 24 in this case from November of 2017 in which you 25 were listed formally and publicly as an expert</p>

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<p style="text-align: right;">Page 194</p> <p>1 for the MDL? Have you seen that document?</p> <p>2 A. I'm not sure that I have, actually.</p> <p>3 Q. Were you aware that in November of</p> <p>4 2017, you were listed on a court document as an</p> <p>5 expert for the plaintiffs in the MDL litigation?</p> <p>6 MR. ROTMAN: Objection.</p> <p>7 A. I don't know the timing or I don't</p> <p>8 think I saw the document, so I...</p> <p>9 ("The Plaintiffs' Steering</p> <p>10 Committee's Initial Designation and</p> <p>11 Disclosure of Non-case Specific Expert</p> <p>12 Witnesses" marked Exhibit 18.)</p> <p>13 BY MS. AHERN:</p> <p>14 Q. Okay. I'm marking Exhibit 18 to your</p> <p>15 deposition. Do you see this document,</p> <p>16 Exhibit 18, is entitled "Plaintiff Steering</p> <p>17 Committee's Initial Designation and Disclosure of</p> <p>18 Non-case Specific Expert Witnesses"?</p> <p>19 A. Okay.</p> <p>20 Q. And if you turn to -- first of all,</p> <p>21 let's see. Unfortunately, I can't find the date</p> <p>22 on that, and I apologize.</p> <p>23 MR. TISI: It's January, if I'm not</p> <p>24 mistaken. I think it was mid-January of 2017.</p> <p>25 MS. AHERN: Is that what it is?</p>	<p style="text-align: right;">Page 196</p> <p>1 MR. TISI: That's fine.</p> <p>2 MS. AHERN: Absolutely.</p> <p>3 I have the date as November 6, 2017.</p> <p>4 MR. TISI: You are exactly -- well, it</p> <p>5 is what it is.</p> <p>6 MS. AHERN: Okay. Either way.</p> <p>7 BY MS. AHERN:</p> <p>8 Q. Okay. Doctor, if you turn to -- if you</p> <p>9 turn to Page 8, the bottom of Page 8, do you see</p> <p>10 your name?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. And did you -- go ahead and</p> <p>13 review the text here associated with your name</p> <p>14 and designation.</p> <p>15 (Witness complies.)</p> <p>16 Q. Just let me know when you're finished.</p> <p>17 A. I'm finished reading my blurb. I'm</p> <p>18 just looking...</p> <p>19 Q. Sure.</p> <p>20 A. Okay.</p> <p>21 Q. Were you aware in November of 2017 that</p> <p>22 you had been publicly disclosed as an expert on</p> <p>23 behalf of plaintiffs in the MDL?</p> <p>24 MR. TISI: Okay. That's -- and you do</p> <p>25 kind of need to know the context in which this</p>
<p style="text-align: right;">Page 195</p> <p>1 MR. TISI: Yeah. And, Counsel, since I</p> <p>2 was involved in this process, if you don't mind</p> <p>3 if I place an objection here.</p> <p>4 MS. AHERN: Sure.</p> <p>5 MR. TISI: As you may not know, during</p> <p>6 the status conference where this was ordered -- I</p> <p>7 don't have the transcript in front of me -- it</p> <p>8 was intended to be an interim -- I don't know</p> <p>9 what the questions are going to be, but it was</p> <p>10 intended to be an interim disclosure to help</p> <p>11 guide the legal process for identifying issues</p> <p>12 that would be involved in Judge Wolfson looking</p> <p>13 at the science.</p> <p>14 It was never -- I don't know -- again,</p> <p>15 not knowing what your questions are, I don't even</p> <p>16 think it would be intended to be used as an</p> <p>17 expert -- as an exhibit in a deposition.</p> <p>18 But, you know, whatever your questions</p> <p>19 are, we would like to reserve that because --</p> <p>20 MS. AHERN: Sure.</p> <p>21 MR. TISI: -- this was intended to be</p> <p>22 a -- more of an informative document than</p> <p>23 anything else.</p> <p>24 MS. AHERN: Okay. Your objection is</p> <p>25 noted.</p>	<p style="text-align: right;">Page 197</p> <p>1 was done.</p> <p>2 MS. AHERN: I'm just asking if she was</p> <p>3 aware she was publicly -- she was already</p> <p>4 retained at that point.</p> <p>5 MR. TISI: She was retained, but there</p> <p>6 was no -- the judge was very clear when she</p> <p>7 ordered that this be done. She understood that</p> <p>8 this was not a disclosure of experts.</p> <p>9 So when you ask the question "You</p> <p>10 understand you were being identified as an expert</p> <p>11 at that time," she would have no way of knowing</p> <p>12 that because we didn't know it.</p> <p>13 MR. KLATT: Chris, you've got to limit</p> <p>14 your objection.</p> <p>15 MR. TISI: No. But it's unfair</p> <p>16 because --</p> <p>17 MR. KLATT: You're coaching the</p> <p>18 witness. You're telling her the whole story.</p> <p>19 MR. TISI: It's a true story. Why</p> <p>20 don't we ask her to leave, and we'll put it on</p> <p>21 the record. I have no problem with that.</p> <p>22 MR. KLATT: All right.</p> <p>23 MR. TISI: We can ask her to leave, and</p> <p>24 we can put it on the record.</p> <p>25 MR. KLATT: Let's do that.</p>

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<p>1 MR. ROTMAN: Go get a cookie. 2 MS. AHERN: Sorry, doctor. 3 (Witness exited) 4 MS. AHERN: My questions on this are 5 fairly limited to the time period that she was 6 retained, time period she was intending to be an 7 expert, that sort of thing -- 8 MR. TISI: Yeah. 9 MS. AHERN: -- and the subject matter 10 that she is being designated for. 11 MR. TISI: Yeah. But, you see, the 12 issue in the case -- and the reason why this was 13 a tricky issue for the judge and -- well, I won't 14 speak for the judge, but for us when we disclosed 15 this was because we didn't know -- we didn't have 16 expert reports. We didn't even have opinions 17 yet. 18 So this was being done in a way that 19 said, "Okay, Judge, she wants to know, A, are 20 there new and different witnesses that were going 21 to be designated that were different than what 22 was designated in the state court?" 23 MS. AHERN: I do recall this, yes. 24 MR. TISI: The second issue, she was 25 very clear that she understood that there was a</p>	<p>1 MR. TISI: She was probably not, I 2 mean, what she was aware of when she had been 3 retained. 4 MS. AHERN: Did she agree to be 5 disclosed as an expert? 6 MR. TISI: She agreed to be retained. 7 She was disclosed as an expert when she reached 8 her conclusions in the case. 9 And so what the Court was requiring us 10 to do was to give us a broad brush, and she was 11 very clear. I remember standing in court, and 12 she said, "Look, some of these may fall off your 13 list. Some of these may -- we may have people 14 that might be added, but I want a snapshot in 15 time as to what I'm dealing with in terms of" -- 16 MR. KLATT: We don't need to waste time 17 on the record on this. 18 MR. TISI: We can go off the record if 19 you want. I just don't want to be -- use this as 20 an unfair -- you know, none of your questions 21 have been unfair up until now. 22 But to take this document and to 23 suggest in some fashion -- and I don't know what 24 you're going to do with it. Maybe we just need 25 to wait and see.</p>
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<p>1 lot of discovery that needed to be done, 2 documents to be reviewed, science that was going 3 to come out. So she was pretty clear that this 4 was more informative than anything else. 5 And so when you ask her a question 6 about -- when you ask her questions, "You know 7 when this document was disclosed when you were 8 identified as an expert," you know, it implies 9 that she had agreed to be -- you know, what her 10 opinions actually were at that time. 11 She -- I can tell you that these 12 reports were done over a period of time. So it's 13 misleading, and it really is an unfair thing to 14 do to a witness because this was a court request 15 having nothing to do with her opinions or her 16 expert report. 17 MS. AHERN: Okay. 18 MR. TISI: Do you understand where I'm 19 coming from? 20 MS. AHERN: I understand where you're 21 coming from. 22 Here is my question to you: Did Dr. -- 23 was Dr. Kane not aware that you were going to 24 designate her or that you had at least publicly 25 disclosed her to the Court?</p>	<p>1 But I think this is -- I don't think 2 anyone ever intended that this document would be 3 used as an exhibit in a deposition of one of 4 these witnesses. I don't think the court 5 intended that to be the case, just like she -- 6 when she ordered the Tardek report -- 7 informational only. 8 MR. KLATT: Are we off the record? 9 We're just going on here. Let's go off the 10 record. 11 MR. TISI: Yeah. 12 THE VIDEOGRAPHER: Off the record, 13 2:38 p.m. 14 (A recess was taken.) 15 THE VIDEOGRAPHER: Back on the record, 16 2:42 p.m. 17 (Witness returns) 18 BY MS. AHERN: 19 Q. Okay. Doctor, I've just shown you a 20 copy of some early designations that were 21 submitted in the talc MDL, and you saw your name 22 listed as one of the people who was being 23 considered as an expert; correct? 24 A. My name is in this document. Yes. 25 Q. Okay. Is there any -- do you have any</p>

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<p style="text-align: right;">Page 202</p> <p>1 issues with the description of the testimony that 2 you were going to offer to give? 3 A. I believe that to be accurate. 4 Q. Okay. And you had been working on your 5 report at this point since May of 2017; correct? 6 A. I started in May. "Writing the report" 7 is a very loose description. What I was -- what 8 I started, as I mentioned before, was I started 9 to review literature. I sort of took notes. So 10 I sort of counted that as writing. So I started 11 that process in May. 12 Q. Okay. And the only thing I was going 13 to ask you about in this report is, as you look 14 through it, do you note that there are a number 15 of professional epidemiologists that have been 16 listed in this report on behalf of plaintiffs? 17 A. I'd have to go through the list. I 18 actually, even though I did have access to 19 several final reports, after I had submitted my 20 report, I don't remember who was what specialty, 21 what field, for the majority of them. 22 Q. Well, how about this question: Of the 23 experts -- are you aware of which experts have 24 submitted reports on behalf of the plaintiffs? 25 A. I would need to look at the list that I</p>	<p style="text-align: right;">Page 204</p> <p>1 asked me if I would be willing to do an extensive 2 review of the literature and decide what my 3 opinion would be on talcum powder products 4 causing ovarian cancer. 5 Q. Did you ask them or discuss with them 6 what your role would be in terms of your specific 7 area of expertise in anatomic pathology? 8 A. I did not specifically talk to them 9 about that because I know that I'm a gynecologic 10 pathologist, so I thought that would be my area 11 where I weigh in on my opinion. 12 Q. And where in your report specifically 13 do you address your expertise in gynecologic 14 pathology, anatomic pathology? 15 A. I list it in the beginning of my 16 report, I think. I talk about -- I talk about my 17 background. 18 Is that what you mean? 19 Q. I mean more in terms of the opinions 20 that you're giving being informed by your 21 expertise in anatomic pathology. 22 A. Well, again, I'm an expert in 23 gynecologic pathology, and the question is about 24 a causation of ovarian cancer, so certainly that 25 falls into my area of expertise.</p>
<p style="text-align: right;">Page 203</p> <p>1 reviewed, which I think is all of the ones that 2 were submitted, and compare it to this list. 3 I mean, I know Jack Siemiatycki is an 4 epidemiologist, off the top of my head. 5 Dr. Singh, I believe, is an epidemiologist. 6 But without going through the list and sort 7 of jogging my memory as to the reports, I skimmed 8 a lot of these reports. 9 Q. Okay. And I guess the point is: Are 10 you aware, as we sit here today, that the 11 plaintiffs have designated a number of 12 epidemiologists in this MDL litigation who have 13 given reports and/or testimony at this point on 14 the topic of epidemiology, talc and ovarian 15 cancer? 16 A. I am aware that they have 17 epidemiologists that have submitted reports for 18 this MDL. 19 Q. Okay. And specifically, if you can 20 think back to your initial contact with 21 plaintiffs' counsel when you were asked to get 22 involved in the litigation, what specifically 23 were you asked to do, or what was your 24 understanding of what your role would be? 25 A. Yeah. My understanding was they had</p>	<p style="text-align: right;">Page 205</p> <p>1 Q. And do you specifically address in 2 terms of anatomic pathology or ovarian cancer 3 pathogenesis the question of talc and ovarian 4 cancer? 5 A. I think that goes to the plausibility, 6 the mechanisms, as part of it. 7 Q. And which particular mechanisms are 8 informed by the discipline of anatomic pathology 9 and gynecologic pathology? 10 A. Well, I think pathologists, anatomical 11 and clinical pathologists, have training in 12 inflammation and immunology and certainly 13 epidemiology, looking at epidemiologic studies. 14 I think all of it is within the realm of 15 gynecologic pathology. 16 Q. Did you discuss anywhere specifically 17 in your report the biology of foreign body 18 reactions and granulomas as a part of the 19 biologic plausibility for exposure? 20 A. Let me refer to my report. I 21 definitely talk about inflammation. I can do a 22 word search for granulomas, if you would like. 23 Q. Do you talk about inflammation -- 24 MR. ROTMAN: Would you like -- 25 Q. -- in the context of anatomic</p>

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<p style="text-align: right;">Page 206</p> <p>1 pathology?</p> <p>2 MR. ROTMAN: Would you like to do that?</p> <p>3 Because I can get your report up electronically.</p> <p>4 MS. AHERN: I know where she's</p> <p>5 mentioned granulomas. I already know. I'm just</p> <p>6 asking her if she knows.</p> <p>7 MR. ROTMAN: So she wants to find it</p> <p>8 quickly.</p> <p>9 MS. AHERN: You can give her your</p> <p>10 computer and let her search.</p> <p>11 MR. ROTMAN: Okay. That's what I was</p> <p>12 asking.</p> <p>13 BY MS. AHERN:</p> <p>14 Q. Do you cite any publications describing</p> <p>15 the biology of granulomas?</p> <p>16 A. I know some of the literature talks</p> <p>17 about granulomatous inflammation, discusses</p> <p>18 granulomatous inflammation.</p> <p>19 MR. ROTMAN: If you want to search, do</p> <p>20 you know how to do it on this computer? Edit,</p> <p>21 Find, then you can type in a word that you want</p> <p>22 to search.</p> <p>23 MR. KLATT: Is there a question?</p> <p>24 A. So I mention it in the animal studies,</p> <p>25 injecting talc into the pleural spaces causes</p>	<p style="text-align: right;">Page 208</p> <p>1 any other portions of your report that directly</p> <p>2 address ovarian cancer pathogenesis from a</p> <p>3 pathology standpoint," and --</p> <p>4 A. So my answer is I did the work, but I</p> <p>5 can't discuss it because of attorney work product</p> <p>6 issues.</p> <p>7 Q. Okay.</p> <p>8 MR. ROTMAN: You can -- she can -- you</p> <p>9 can ask her questions about it.</p> <p>10 MS. AHERN: Sure.</p> <p>11 MR. ROTMAN: But she's -- as to what is</p> <p>12 in the report or not in the report, that's the</p> <p>13 work product piece.</p> <p>14 MS. AHERN: That's kind of all the</p> <p>15 questions.</p> <p>16 MR. ROTMAN: Ask her about the science.</p> <p>17 MS. AHERN: I'll ask, and you can</p> <p>18 object.</p> <p>19 MR. KLATT: Find out what is in or is</p> <p>20 not in the report.</p> <p>21 MS. AHERN: Let's pick up the</p> <p>22 foundation here.</p> <p>23 BY MS. AHERN:</p> <p>24 Q. Doctor, first of all, you said you did</p> <p>25 the work relating to ovarian cancer pathogenesis</p>
<p style="text-align: right;">Page 207</p> <p>1 granulomatous response. It looks like those are</p> <p>2 the two.</p> <p>3 And then I cite the Mostafa 1985 paper,</p> <p>4 "Foreign body granulomas in normal ovaries."</p> <p>5 I'm double-checking. It looks like in doing</p> <p>6 a word search for granuloma, that's what is</p> <p>7 popping up.</p> <p>8 BY MS. AHERN:</p> <p>9 Q. Okay. Are there any other portions of</p> <p>10 your report that directly address ovarian cancer</p> <p>11 pathogenesis from a pathology standpoint?</p> <p>12 MR. ROTMAN: Objection.</p> <p>13 A. This might be attorney work product</p> <p>14 draft stuff.</p> <p>15 MR. ROTMAN: Do you want to talk to me</p> <p>16 outside where I can understand what you're</p> <p>17 getting at?</p> <p>18 THE WITNESS: Sure. Sure.</p> <p>19 THE VIDEOGRAPHER: Off the record,</p> <p>20 2:50 p.m.</p> <p>21 (A recess was taken.)</p> <p>22 THE VIDEOGRAPHER: Back on the record,</p> <p>23 2:54 p.m.</p> <p>24 BY MS. AHERN:</p> <p>25 Q. Okay. Doctor, I had asked: "Are there</p>	<p style="text-align: right;">Page 209</p> <p>1 from a pathology standpoint; correct?</p> <p>2 A. Yes.</p> <p>3 Q. Was it ever in your report?</p> <p>4 MR. ROTMAN: That's part of the work</p> <p>5 product objection.</p> <p>6 MR. KLATT: We've got to establish the</p> <p>7 facts to know whether there's a basis to assert</p> <p>8 the objection.</p> <p>9 MR. ROTMAN: You can ask the question.</p> <p>10 But in order to answer the question, you're</p> <p>11 invading the domain of what is protected under</p> <p>12 the Federal Rules in terms of the drafting of</p> <p>13 expert reports.</p> <p>14 I will object and instruct her not to</p> <p>15 answer.</p> <p>16 What's in the report, you have. What</p> <p>17 was in drafts of the report, you're not entitled</p> <p>18 to.</p> <p>19 So that's the problem we have.</p> <p>20 MR. KLATT: She's not asking what was</p> <p>21 in the report. She's asking whether it was or</p> <p>22 isn't. So we can establish if there's anything</p> <p>23 to even have a dispute about.</p> <p>24 MR. ROTMAN: You can ask her about what</p> <p>25 is in the report all you want.</p>

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<p style="text-align: right;">Page 210</p> <p>1 MS. AHERN: Well, she's already said 2 there was a section on ovarian cancer 3 pathogenesis from a pathology standpoint in the 4 report, and it was removed; correct? 5 MR. TISI: That's not what she 6 testified. 7 MS. AHERN: Read back. 8 MR. TISI: Why don't we read what she 9 said because she said the answer is: 10 "ANSWER: I did the work, but I can't 11 discuss it because of attorney work product." 12 MS. AHERN: Okay. Okay. 13 MR. TISI: She never said it was in the 14 report. 15 MS. AHERN: Thank you. 16 MR. TISI: Line 48. 17 BY MS. AHERN: 18 Q. When you say you "did the work," did 19 you take any notes on any reading that you did on 20 ovarian cancer pathogenesis? 21 A. So in writing this report, I generally 22 did not take any notes, handwritten notes. It 23 was sort of a living document that I used. 24 Q. Now, earlier, you referred several 25 times to taking notes as you were going through</p>	<p style="text-align: right;">Page 212</p> <p>1 let me rephrase it. 2 As a gynecologic pathologist who was asked 3 to opine on ovarian cancer and talc, did you 4 assume that part of your opinions would be to 5 incorporate your expertise in anatomic pathology 6 and gynecologic pathology? 7 MR. ROTMAN: Wait. Wait. Wait. Wait. 8 Wait. 9 MS. AHERN: I'm only concerned if she 10 understands the question. 11 BY MS. AHERN: 12 Q. Do you understand the question? 13 MR. ROTMAN: No. You have to let me 14 see if I understand the question to see if I'm 15 going to object to it before she's allowed to 16 answer. 17 MS. AHERN: Why don't you make an 18 objection, and we'll move on. 19 MR. TISI: Because he may instruct her 20 not to answer the question. 21 MS. AHERN: This is not -- this is not 22 a question that should invade your privilege. 23 MR. TISI: It involves the discussion 24 between counsel and in the drafting of the 25 reports, what would be in, what would be out,</p>
<p style="text-align: right;">Page 211</p> <p>1 literature. 2 Are all those notes something that became -- 3 on a single document that ultimately became a 4 report? 5 A. It was one document that went through 6 numerous, numerous editing on my part and, of 7 course, suggestions from attorneys at different 8 points. 9 Q. Now, as an anatomic pathologist and as 10 the only pathologist that has been designated by 11 the plaintiffs in this MDL, did you think that it 12 was important to opine on the pathogenesis of 13 ovarian cancer from an anatomic pathology 14 standpoint? 15 MR. ROTMAN: Objection. For what 16 purpose? 17 MS. AHERN: I'm asking her. 18 Q. Can you answer the question? 19 A. First of all, I wasn't aware I was the 20 only pathologist because I didn't have a list of 21 their named experts. 22 I did work on -- I'm not sure how much I can 23 really talk about the whole draft process. 24 MR. ROTMAN: You can't -- 25 Q. So my question was: As an anatomic --</p>	<p style="text-align: right;">Page 213</p> <p>1 what she thought, what she didn't think. You're 2 not entitled to any of that. 3 MR. ROTMAN: So if you can find the 4 question, read the question, and I will object to 5 the question, but you can answer it. 6 A. Okay. So you want me to reread the 7 question? 8 MR. ROTMAN: To yourself. 9 So my question was -- do you see that? 10 THE WITNESS: Yeah. 11 A. Well, I feel as if I did that in my 12 final report. I certainly -- the -- my opinions 13 that are in my final report are certainly within 14 the realm of gynecologic pathology. 15 Q. And can you specifically point to the 16 opinions and the discussions in your report that 17 are within your personal expertise in gynecologic 18 pathology? 19 A. So, again, review of epidemiology is 20 something that physicians do on a regular basis. 21 We're trained to look at epi data. We're trained 22 to practice evidence-based medicine, which has a 23 very similar, if not identical, methodology. 24 So -- and we certainly are trained in 25 inflammation, the immune system, talc and</p>

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<p>1 tissue -- I have a section on talc and tissue --</p> <p>2 the epi data.</p> <p>3 Not -- I don't think any of this report is</p> <p>4 outside of my -- I know that none of this is</p> <p>5 outside of my expertise as a gynecologic</p> <p>6 pathologist.</p> <p>7 Q. Okay. Doctor, were you retained as an</p> <p>8 expert epidemiologist in this case?</p> <p>9 A. I was retained as a gynecologic</p> <p>10 pathologist.</p> <p>11 Q. And you are not an epidemiologist;</p> <p>12 correct?</p> <p>13 A. I'm not a epidemiologist, but we</p> <p>14 certainly review epidemiology and critique</p> <p>15 epidemiology studies on a regular basis in our</p> <p>16 daily practice.</p> <p>17 Q. When people ask you what you do for a</p> <p>18 living, you don't tell them you're an</p> <p>19 epidemiologist, do you?</p> <p>20 A. I often have to explain what a</p> <p>21 pathologist is, so I spend half the time just</p> <p>22 trying to describe what a pathologist is, so...</p> <p>23 MR. KLATT: Objection. Nonresponsive.</p> <p>24 MS. AHERN: Yeah.</p> <p>25 MR. ROTMAN: She's not done answering</p>	<p>1 Q. You do a full systematic review of the</p> <p>2 literature, as that term is defined</p> <p>3 epidemiologically?</p> <p>4 A. We certainly do when we're doing</p> <p>5 research, when we're writing papers, but we still</p> <p>6 do literature searches when we're assigning out</p> <p>7 cases that are relevant to individual patients.</p> <p>8 Q. When was the last time you conducted a</p> <p>9 full systematic review of the literature and a</p> <p>10 Bradford Hill analysis to opine on causation?</p> <p>11 A. So, again, this is not something that's</p> <p>12 completely foreign to me. The legal aspect of it</p> <p>13 is new to me, but this methodology is not new to</p> <p>14 me.</p> <p>15 The last time -- I mean, there was a tobacco</p> <p>16 case that I worked on, but in my daily practice,</p> <p>17 again, I'm still looking at epidemiology</p> <p>18 literature all the time.</p> <p>19 Q. Well, there is a difference, Doctor,</p> <p>20 wouldn't you agree, between looking at the</p> <p>21 epidemiology to inform yourself about a</p> <p>22 particular issue and doing a systematic review of</p> <p>23 the literature and a full Bradford Hill analysis</p> <p>24 to opine on causation? Is there a difference?</p> <p>25 A. Well, this was a deep dive, so I'll say</p>
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<p>1 your question. She's in the middle of an answer.</p> <p>2 A. So my point is I'm unlikely to describe</p> <p>3 myself as an epidemiologist when I'm trying to</p> <p>4 describe what a pathologist does, but that's the</p> <p>5 big picture.</p> <p>6 But the real picture is, on a daily basis,</p> <p>7 we are evaluating epidemiologic data in the</p> <p>8 literature.</p> <p>9 BY MS. AHERN:</p> <p>10 Q. When was the last time you did a</p> <p>11 systematic review of the literature for the</p> <p>12 purpose of opining on causation?</p> <p>13 A. So we review literature --</p> <p>14 Q. You. I'm just talking about you.</p> <p>15 A. Hold on one second. Let me just review</p> <p>16 the question. I'm way behind here on my --</p> <p>17 Well, I do literature searches all the time</p> <p>18 and looking -- when I'm looking at cases to</p> <p>19 figure out causation.</p> <p>20 I've been involved in one other legal case,</p> <p>21 but it is -- this was the first medical-legal</p> <p>22 general causation report.</p> <p>23 But, again, this is all the same methodology</p> <p>24 that we use in evidence-based medicine and our</p> <p>25 practice.</p>	<p>1 I was aware of the literature on talcum powder</p> <p>2 and ovarian cancer before I became involved in</p> <p>3 this litigation.</p> <p>4 I will say, you know, it wasn't until they</p> <p>5 asked me to form my opinion on this that I did a</p> <p>6 deep dive on the literature again on this</p> <p>7 particular issue.</p> <p>8 Again, I've certainly done extensive</p> <p>9 literature reviews before to, you know -- in</p> <p>10 research and in practice.</p> <p>11 Q. But nothing like this?</p> <p>12 A. It's very similar.</p> <p>13 MR. ROTMAN: Objection.</p> <p>14 A. The methodology is very similar to</p> <p>15 this. It's identical.</p> <p>16 Q. Doctor, can you point me to -- take a</p> <p>17 look at Exhibit 2, your CV.</p> <p>18 Can you point me to something in your CV</p> <p>19 that demonstrates some specialized knowledge or</p> <p>20 expertise in epidemiology? A course, a class</p> <p>21 you've taught? A paper that you've published? A</p> <p>22 case-control study you've been involved in?</p> <p>23 Anything that would indicate that you have</p> <p>24 specialized expertise in epidemiology?</p> <p>25 A. It's part of our medical training as</p>

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<p style="text-align: right;">Page 218</p> <p>1 part of evidence-based medicine.  2 I'm trying to find my CV. I'm not sure I  3 have it in front of me. Maybe it's under here.  4 Well, you're sitting in -- I mean, all of these  5 involved epidemiology research.  6 MR. ROTMAN: All of what?  7 A. I'm sorry. All of these research  8 projects start with -- the pathology publications  9 start with looking at the literature of  10 epidemiology.  11 Q. Which ones are you pointing to --  12 sorry. Let's look at the peer-reviewed  13 publications.  14 Is that what you're talking about?  15 A. Yes. Sorry.  16 Q. So the first publication is Narasimhan,  17 "Temperature Induced Interstrand Crosslinks in  18 Cisplatin-DNA Adducts Detected by Electrophoresis  19 and UV Spectrophotometer."  20 That's not an epi study, is it?  21 A. Some of these were biology. The one  22 that comes to mind when I'm looking at this list  23 is the "Yersinia pestis and the plague." That  24 was a review article. That was around -- that  25 was after the 2001 mailings of the pattern</p>	<p style="text-align: right;">Page 220</p> <p>1 So that was sort of more the review on that.  2 Q. Who is S.M. Rollins?  3 A. That's my ex-husband.  4 Q. What is his specialty?  5 A. He's a microbiologist.  6 Q. What about Ryan?  7 A. He is an infectious disease physician.  8 Q. Okay. What portion of "Yersinia pestis  9 and the plague" did you draft or did you  10 contribute?  11 A. I drafted the entire -- I was the lead  12 author, and I -- the primary author, and I  13 drafted that report.  14 Q. Okay. So if we go in there, we're  15 going to find you used statistical methods or  16 analysis in any way to weigh the evidence and  17 conduct a systematic review?  18 A. It's definitely a review article. Off  19 the top of my head, I don't know if I did a  20 statistical analysis, but...  21 Q. Would you describe it as more of a  22 narrative review of the literature?  23 A. A review of the literature. I don't  24 know about the word "narrative," but review.  25 Q. What about the Grundy paper,</p>
<p style="text-align: right;">Page 219</p> <p>1 substance. And so the literature was very  2 interested in Yersinia pestis at the time, and so  3 I did a review article on that.  4 Q. Was that a systematic review and a  5 Bradford Hill analysis?  6 A. The Bradford Hill analysis is part of  7 evidence-based medicine when you're coming to a  8 conclusion. So --  9 Q. This isn't a case-control study or a  10 prospective cohort study --  11 MR. ROTMAN: You're not allowing her to  12 finish her answer.  13 Q. -- or epidemiology study, is it?  14 A. But my general causation opinion is  15 very similar to a review article on causation.  16 It's a review of the epi data and mechanisms.  17 Q. Did you do a full review of the epi  18 data and mechanisms on Yersinian plague?  19 It's kind of a done deal; right? We already  20 know that; isn't that right?  21 A. Well, you're still looking at -- you're  22 still looking at data. The question is -- the  23 question was at the time: Can Yersinia pestis be  24 a dangerous weapon of destruction or  25 terrorist-type agent?</p>	<p style="text-align: right;">Page 221</p> <p>1 "Specificity of tRNA-mRNA Interactions in  2 Bacillus subtilis tyrS Antitermination"?  3 Is that an epi study?  4 A. No.  5 Q. What about the Rollins paper,  6 "Diagnostic yield of muscle biopsy in patients  7 with clinical evidence of mitochondrial  8 cytopathy"?  9 Is that an epidemiologic article?  10 A. No. That's not an epidemiology  11 article, but we --  12 Q. Sorry?  13 A. It's getting late in the day.  14 MR. TISI: Do you need some water?  15 THE WITNESS: Sure.  16 A. But it's interesting that it actually  17 did involve electron microscopy. And when we do  18 muscle biopsies for mitochondrial cytopathy, we  19 use electron microscopy anyway, regularly.  20 MR. KLATT: Objection. Nonresponsive.  21 Q. And what about the Rollins  22 "Autoimplants and serous borderline tumors of the  23 ovary: A clinicopathologic study of 30 cases and  24 a process to be distinguished from serous  25 adenocarcinoma"?</p>

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<p style="text-align: right;">Page 222</p> <p>1 Was that a systematic review of the</p> <p>2 literature, or an epidemiologic study?</p> <p>3 A. There's definitely review of literature</p> <p>4 as part of that study because the question arises</p> <p>5 with autoimplants, sometimes they're misdiagnosed</p> <p>6 as invasive serous.</p> <p>7 So there is definitely literature review for</p> <p>8 that study.</p> <p>9 Q. This would be described as you have it</p> <p>10 in the title, this is a clinicopathologic study?</p> <p>11 A. Correct.</p> <p>12 Q. So you were looking at this as a</p> <p>13 pathologist; correct?</p> <p>14 A. Well, I'm looking at -- I mean, some of</p> <p>15 these were before I was -- the first couple are</p> <p>16 before I was an M.D., but all of the subsequent</p> <p>17 ones I'm looking at as a pathologist.</p> <p>18 Q. What about the Chan study,</p> <p>19 "Clinicopathologic Correlation of Fetal Vessel</p> <p>20 Thrombosis in Mono- and Dichorionic Twin</p> <p>21 Placentas"?</p> <p>22 Is that an epidemiologic study?</p> <p>23 A. That's a clinicopathologic correlation.</p> <p>24 Q. And then the publication with Jonathan</p> <p>25 Hecht, "Endometrial Interepithelial Neoplasia,"</p>	<p style="text-align: right;">Page 224</p> <p>1 are degreed epidemiologists who have been</p> <p>2 designated on behalf of plaintiffs to look at</p> <p>3 these issues; correct?</p> <p>4 A. I'm aware of that now. I didn't know</p> <p>5 who their list was before I submitted my report.</p> <p>6 Q. You've never published -- as we just</p> <p>7 looked through here -- an epidemiologic study, a</p> <p>8 case-control study, or a cohort study?</p> <p>9 A. I have not published; but, again, that</p> <p>10 doesn't -- I mean, it doesn't mean I haven't done</p> <p>11 them. It's just that --</p> <p>12 Q. Have you done them?</p> <p>13 A. They haven't been published. Well,</p> <p>14 again, literature reviews of epidemiology is part</p> <p>15 of our regular practice.</p> <p>16 Q. I'm asking about, like, actual study</p> <p>17 designs.</p> <p>18 Have you conducted a case-control or a</p> <p>19 cohort study?</p> <p>20 A. Not of an epi- --</p> <p>21 Q. Okay.</p> <p>22 A. -- specific design.</p> <p>23 Q. Have you ever taught an epidemiology</p> <p>24 course?</p> <p>25 A. No.</p>
<p style="text-align: right;">Page 223</p> <p>1 is that an epidemiology study?</p> <p>2 A. That was a review of a new terminology</p> <p>3 in endometrial precursor lesions. So that was a</p> <p>4 pathologic -- an anatomic pathology article.</p> <p>5 Q. And then you have the one with Haspel,</p> <p>6 which is "Successful Implementation of a</p> <p>7 Longitudinal, Integrated Pathology Curriculum</p> <p>8 During the Third Year of Medical School"?</p> <p>9 A. That was a medical-education-type</p> <p>10 article.</p> <p>11 Q. Okay. And do you have any proceedings</p> <p>12 of meetings, poster presentations, that were from</p> <p>13 a case-control or a cohort study that you</p> <p>14 conducted?</p> <p>15 A. Let me look. I don't believe these</p> <p>16 poster presentations were case -- well, I mean,</p> <p>17 case-control or cohort epi-type studies.</p> <p>18 Q. Okay. And, Doctor, to be fair, you</p> <p>19 don't have a degree in epidemiology; correct?</p> <p>20 A. I do not have a degree. But, again,</p> <p>21 it's -- epidemiology is a very big part of</p> <p>22 evidence-based medicine and what we practice as</p> <p>23 M.D.s.</p> <p>24 MR. KLATT: Objection. Nonresponsive.</p> <p>25 Q. And, Doctor, you understand that there</p>	<p style="text-align: right;">Page 225</p> <p>1 Q. Do you have any grant funding to</p> <p>2 conduct epidemiologic observational studies?</p> <p>3 A. No.</p> <p>4 Q. Have you ever given any lectures or</p> <p>5 presentations specifically on epidemiology</p> <p>6 methodologies?</p> <p>7 A. That's possible. I'm trying to think.</p> <p>8 It's been a long time. Medical school through</p> <p>9 residency, fellowship, not that I can think of</p> <p>10 off the top of my head.</p> <p>11 Q. Okay. And have you ever designed a</p> <p>12 clinical trial?</p> <p>13 A. I have not designed a clinical trial.</p> <p>14 Q. Have you designed a case-control study?</p> <p>15 A. I have not designed a case-control</p> <p>16 study.</p> <p>17 Q. Have you designed a cohort study?</p> <p>18 A. I have not designed a cohort study;</p> <p>19 but, again, these are -- we can critically</p> <p>20 evaluate. Just because I haven't designed one</p> <p>21 doesn't mean I can't critically evaluate</p> <p>22 case-control studies or cohort studies.</p> <p>23 Q. Doctor, you haven't conducted a</p> <p>24 meta-analysis or a pooled analysis to evaluate</p> <p>25 potential risk factors for any disease, have you?</p>

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<p>1 A. No, I haven't.</p> <p>2 Q. Are you qualified to conduct a</p> <p>3 meta-analysis or a pooled analysis?</p> <p>4 A. I'm -- I'm sure I could develop one.</p> <p>5 Q. As we sit here today, are you qualified</p> <p>6 to conduct a meta-analysis or a pooled analysis?</p> <p>7 A. If it was sort of a joint venture, I'm</p> <p>8 sure; but, again, that doesn't mean that I can't</p> <p>9 critically evaluate them, because that's what I</p> <p>10 do on a daily basis.</p> <p>11 Q. Have you authored any paper or</p> <p>12 conducted a study -- well, have you authored any</p> <p>13 paper on the methods of causal interpretation?</p> <p>14 A. Have I authored a paper on the methods</p> <p>15 of causal interpretation?</p> <p>16 I don't believe I've authored. It would be</p> <p>17 on my list.</p> <p>18 Q. Okay. Doctor, I should have asked you</p> <p>19 this when it was in front of you: Do you have a</p> <p>20 copy of that one-page additional materials?</p> <p>21 A. Probably. Let's see.</p> <p>22 Q. Thank you. Maybe I have. Maybe I have</p> <p>23 it too.</p> <p>24 A. Exhibit 17?</p> <p>25 Q. Yes. Yes.</p>	<p>1 asbestos in it, that would certainly add to the</p> <p>2 plausibility of causation.</p> <p>3 Q. If there was not asbestos in talcum</p> <p>4 powder products and there was not fragrance in</p> <p>5 talcum powder products and you were just left</p> <p>6 with the pharmaceutical-grade talc, what would</p> <p>7 your biologic plausibility argument be?</p> <p>8 MR. ROTMAN: Objection.</p> <p>9 Q. In other words, what is your mechanism</p> <p>10 by which pharmaceutical-grade talc would cause</p> <p>11 ovarian cancer?</p> <p>12 MR. ROTMAN: Objection. Are you asking</p> <p>13 about causation or about biological plausibility?</p> <p>14 MS. AHERN: I'm asking --</p> <p>15 MR. ROTMAN: You mixed them.</p> <p>16 MS. AHERN: -- about her mechanism.</p> <p>17 BY MS. AHERN:</p> <p>18 Q. What is your mechanism by which</p> <p>19 pharmaceutical-grade talc would cause ovarian</p> <p>20 cancer?</p> <p>21 A. So there are -- again, most of the</p> <p>22 studies are dealing with talc powder products.</p> <p>23 If we were to say that all that was in there is</p> <p>24 pharmaceutical -- it's completely hypothetical</p> <p>25 because I don't know what's in there -- I still</p>
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<p>1 You received a copy of the Longo</p> <p>2 supplemental report; correct?</p> <p>3 A. I did. Yes.</p> <p>4 Q. And it's, what, 404 pages?</p> <p>5 A. That's possible. I don't think I</p> <p>6 looked.</p> <p>7 Q. That was my next question: Did you</p> <p>8 review it?</p> <p>9 A. I did review it. I did skim a lot of</p> <p>10 it because, again, it was additional information</p> <p>11 that was nice to have, but it was after my</p> <p>12 report.</p> <p>13 And, again, my general causation opinion is</p> <p>14 not dependent on asbestos being in the product.</p> <p>15 My general causation opinion is based on whatever</p> <p>16 is in the bottle. So it was interesting</p> <p>17 information to have.</p> <p>18 Q. So your opinions here, it doesn't</p> <p>19 matter for your opinions whether or not there's</p> <p>20 asbestos in talcum powder products; is that your</p> <p>21 testimony?</p> <p>22 A. What I'm saying is my opinion is based</p> <p>23 on whatever is in the talcum powder product's</p> <p>24 bottle. Now, it's up to the jury to decide if</p> <p>25 there's asbestos in it. However, if there is</p>	<p>1 think the mechanisms would be similar where, you</p> <p>2 know, there's evidence that talc can cause</p> <p>3 inflammation, and we know that inflammation is a</p> <p>4 cause of cancer.</p> <p>5 And so I -- and there's also, you know,</p> <p>6 Dr. Cramer talked about anti-MUC-1 antibodies, so</p> <p>7 there's an immune -- plausible immune mechanism,</p> <p>8 so I think all of those are still on the table</p> <p>9 and the hypothetical situation that it's only</p> <p>10 pharmaceutical-grade talc in that bottle.</p> <p>11 But, again, I -- I'm not opining about what</p> <p>12 is in the bottle; I'm just opining about that --</p> <p>13 whatever that product is in that bottle causing</p> <p>14 ovarian cancer.</p> <p>15 Q. Okay. Let's take a look at your expert</p> <p>16 report again, Exhibit 14, if you will.</p> <p>17 Just let me know when you've got it.</p> <p>18 A. Yeah.</p> <p>19 Q. Okay. Doctor, does Exhibit 14, your</p> <p>20 November 15, 2018, expert report, contain all of</p> <p>21 the opinions that you intend to offer as a</p> <p>22 witness in this matter?</p> <p>23 A. I wouldn't box myself in that way.</p> <p>24 There might be questions that I'm asked here</p> <p>25 today or in trial that aren't necessarily in my</p>

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<p>1 report.</p> <p>2 Q. Okay. But the opinions that you intend</p> <p>3 to offer, absent somebody asking you to offer</p> <p>4 other opinions, are all outlined or contained</p> <p>5 within Exhibit 14, your report; is that correct?</p> <p>6 A. Again, I wouldn't want to say "all." I</p> <p>7 wouldn't want to limit myself. There's always</p> <p>8 the possibility that something else will come up,</p> <p>9 and I even have a thing that additional</p> <p>10 information may come up.</p> <p>11 Q. Okay. As we sit here today, do you</p> <p>12 understand that this is our opportunity to ask</p> <p>13 you about the opinions in your report, and we</p> <p>14 have the day to do it?</p> <p>15 Do you understand that?</p> <p>16 A. I understand.</p> <p>17 Q. Okay. So to the extent that you think</p> <p>18 you're going to offer additional opinions or</p> <p>19 different opinions, we need to know that today.</p> <p>20 I understand that if something comes up two</p> <p>21 weeks from now and it's additional information,</p> <p>22 you might supplement your report.</p> <p>23 But as of today, as we sit here today, is</p> <p>24 this report an accurate reflection of the</p> <p>25 opinions that you have formed and that you intend</p>	<p>1 probably have within them all the references to</p> <p>2 your report. Other than those and what you</p> <p>3 brought with you today, is there anything else</p> <p>4 related to your work on your report that you have</p> <p>5 in your possession that you haven't been able to</p> <p>6 bring with you today?</p> <p>7 A. Not that I'm aware of. I've tried to</p> <p>8 be very complete in my list of what I reviewed.</p> <p>9 It's possible -- again, it's possible there are a</p> <p>10 couple of things that might have been left off,</p> <p>11 but I tried to be as complete as possible.</p> <p>12 Q. Okay. And you mentioned earlier you</p> <p>13 had done some work on the pathogenesis of ovarian</p> <p>14 cancer.</p> <p>15 Did you have any articles or publications</p> <p>16 that are related to that work that are not</p> <p>17 referenced in your report?</p> <p>18 A. I believe they should be in the list.</p> <p>19 They should be included in the list that you</p> <p>20 have.</p> <p>21 Q. The one from -- your initial report?</p> <p>22 A. Taken all together. Taken all</p> <p>23 together. So that, probably, is more -- the</p> <p>24 January 4th one would probably be some of those.</p> <p>25 And then I can't remember what's on that one</p>
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<p>1 to offer in this case?</p> <p>2 A. I would say it's an accurate reflection</p> <p>3 of the opinions I have formed with the exception</p> <p>4 of anything that might be asked that is not in</p> <p>5 the report; but yes.</p> <p>6 Q. All right. All right.</p> <p>7 And as we sit here today, is your report</p> <p>8 complete?</p> <p>9 A. Well, it's signed and turned in, so --</p> <p>10 Q. Do you, as the expert designated in</p> <p>11 this case, Sarah Kane, do you consider your</p> <p>12 report to be complete as we sit here today?</p> <p>13 A. Yes.</p> <p>14 MR. ROTMAN: Off the record.</p> <p>15 (Discussion off the record.)</p> <p>16 THE VIDEOGRAPHER: Off the record,</p> <p>17 3:24 p.m.</p> <p>18 (A recess was taken.)</p> <p>19 THE VIDEOGRAPHER: Here begins Media</p> <p>20 No. 5 in today's deposition of Sarah Kane, M.D.</p> <p>21 Back on the record, 3:39 p.m.</p> <p>22 BY MS. AHERN:</p> <p>23 Q. Okay. Dr. Kane, we were talking about</p> <p>24 your report. Just some basic housekeeping first.</p> <p>25 We have the four boxes back here which</p>	<p>1 that you just got, but if there's a couple on</p> <p>2 there.</p> <p>3 But I would think if they weren't cited in</p> <p>4 the report, the majority of those should be in</p> <p>5 the January 4th list.</p> <p>6 Q. Okay. And those would pertain to the</p> <p>7 various histologic categorizations of ovarian</p> <p>8 cancer; what is known about etiology.</p> <p>9 Is that kind of the gist of the information</p> <p>10 that you researched?</p> <p>11 A. Yes. Yes. That was certainly part of</p> <p>12 it.</p> <p>13 Q. And were there other parts to that?</p> <p>14 THE WITNESS: Is that -- I don't know</p> <p>15 if --</p> <p>16 MR. ROTMAN: Yeah. You can say what</p> <p>17 work you did.</p> <p>18 A. There was -- so a good bit of it was</p> <p>19 sort of background information on the pathologic</p> <p>20 diagnosis of ovarian cancer and different, as you</p> <p>21 said, different subtypes.</p> <p>22 There was -- I'm trying to remember -- it</p> <p>23 was so long ago -- what some of the -- I believe</p> <p>24 there was a little bit more on inflammation, but</p> <p>25 I can't say for sure.</p>

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<p>1 BY MS. AHERN: 2 Q. And would that have been just related 3 to ovarian cancer pathogenesis? 4 A. Yes. Yes. 5 Q. And you think that all of the 6 publications that you found, identified, reviewed 7 in relation to that work are identified in one of 8 the lists or across several lists? 9 A. I'm hoping that across all of the 10 lists, that encompasses the vast majority, if not 11 all. But let's just keep it at vast majority. 12 And, of course, you know, I'm a gynecologic 13 pathologist, so I read tons of other stuff that, 14 you know, is just my background knowledge that 15 I'm not going to put on these lists. So I can't 16 say it's all-inclusive; but, again, I tried. 17 Q. Understood. Understood. 18 And you've now seen at least one report from 19 Dr. Robert Kurman; correct? 20 A. That's correct. That was an individual 21 causation report, though. So... 22 Q. And he had a very large background 23 section on ovarian cancer pathogenesis; correct? 24 A. To be honest with you, I sort of 25 skimmed it, but I do remember seeing a section on</p>	<p>1 Exhibit 14, your expert report, are they solely 2 the product of your own work? 3 A. Yes. I wrote the report. Certainly, 4 again, there were drafts that went back and 5 forth. There may have been suggestions from 6 attorneys where language was -- that I accepted 7 into my report; but yes. 8 Q. Okay. You didn't borrow language from 9 other experts or from other publications and then 10 not quote that in your report? 11 A. I certainly tried not to. No. I 12 certainly cited anything that I -- I tried to 13 cite everything that I referenced -- 14 Q. Okay. 15 A. -- to the best of my ability. 16 You know, again, I was taking the notes as I 17 wrote, so it's plausible there might be 18 something, but I was very cognizant of trying not 19 to -- trying to cite everything that I was 20 referencing. 21 Q. And in reaching your opinions, was it 22 important to you that you review the data in a 23 fair and objective way? 24 A. Yes. I think it's always important to 25 review data in a fair and objective way.</p>
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<p>1 that. Yes. 2 Q. Okay. Did you skim the section that 3 was case-specific? 4 A. No. Mostly the background since I 5 already know that stuff. 6 Q. Okay. And is the stuff that was in his 7 background section similar to the research that 8 you did? 9 A. I would say yes. If I am remembering 10 accurately, it was similar. I wouldn't say 11 identical, but similar. 12 Q. Okay. And did anyone other than your 13 attorneys assist you in preparing the report? 14 A. No. 15 Q. And you said earlier, I think, that you 16 didn't consult with any of the other experts in 17 the MDL litigation in forming your opinions or 18 preparing your report? 19 A. That's correct. 20 Q. And you didn't review any draft reports 21 from any other experts in this litigation? 22 A. No. The only time I saw their reports 23 was after we had all turned them in to the court. 24 Q. Okay. And are all of the words, the 25 ideas, the analysis that's contained in</p>	<p>1 Q. I know. It's kind of a basic question. 2 When you were doing your literature reviews 3 and searches, were you looking both for papers or 4 data that supported talc and ovarian cancer 5 connection as well as for data and literature 6 that did not or that -- well, that did not 7 support? 8 A. When I was doing my literature search, 9 I was looking for any data that spoke to talcum 10 powder products and ovarian cancer. I was really 11 trying to cast as wide a net as possible to get 12 as much data as I could. 13 Now, certainly, there are limitations when 14 you're doing searches. It's possible there are 15 studies that I missed; but when I was retrieving 16 studies, reading them, I would also reference 17 their references as a sort of cross-check. So I 18 tried to be as complete as I could. 19 Q. So when you were reading someone else's 20 work and they referenced an article as the basis 21 for synthesis or the statement in their paper, 22 did you then go and review the underlying 23 reference as well? 24 A. Yes. I pulled up those references. 25 Q. Okay. And you reviewed those as well?</p>

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<p style="text-align: right;">Page 238</p> <p>1 A. Yes.</p> <p>2 Q. Okay. And you mentioned on Page 4 of</p> <p>3 your report that your interest in talc and</p> <p>4 ovarian cancer began during your training, your</p> <p>5 fellowship training, at Mass General; is that</p> <p>6 right?</p> <p>7 A. I became aware of it. I mean, both</p> <p>8 Dr. Scully and Dr. Bell were still there at my</p> <p>9 time of training, and Dr. Scully was a coauthor</p> <p>10 on Cramer's first 1982 paper.</p> <p>11 And then Dr. Bell was a coauthor in one of</p> <p>12 the subsequent -- I think his 1992 paper with</p> <p>13 Harlow.</p> <p>14 So I was certainly aware of literature on</p> <p>15 talcum powder and ovarian cancer.</p> <p>16 Q. And neither one of them published</p> <p>17 anything else on talc; is that correct?</p> <p>18 A. I believe those were the only two that</p> <p>19 they were on. That's correct.</p> <p>20 Q. And did you understand that the role</p> <p>21 that Dr. Scully played on Dr. Cramer's first</p> <p>22 publication was simply that of pathologist and</p> <p>23 determining or confirming the diagnosis of the</p> <p>24 samples that were being studied?</p> <p>25 A. I was aware that he did a pathologic</p>	<p style="text-align: right;">Page 240</p> <p>1 I know we talked about the Nurses' Health Study.</p> <p>2 That's funny, though, I actually did talk --</p> <p>3 I saw Jonathan last night, so it's kind of funny</p> <p>4 timing. But anyway...</p> <p>5 Q. Have you talked to Dr. Hecht since</p> <p>6 then, since you first discussed with him the</p> <p>7 Nurses' Health Study?</p> <p>8 Have you spoken with him on talc and ovarian</p> <p>9 cancer?</p> <p>10 A. Yes. I saw him last night. We went</p> <p>11 out for a drink.</p> <p>12 Q. Did he give you any opinions on what he</p> <p>13 thought about talc and ovarian cancer?</p> <p>14 A. He told me that he had met with defense</p> <p>15 counsel at one point; did not want to do medical</p> <p>16 expert witness work but did a brief sort of</p> <p>17 intro, I guess, overview for the defense.</p> <p>18 Q. Did he tell you what his personal or</p> <p>19 his professional opinion was on whether or not</p> <p>20 talc causes ovarian cancer?</p> <p>21 A. Yes. He thought that -- so I'll say in</p> <p>22 my report, I did not spend a lot of time on</p> <p>23 migration because in the gynecologic world, it's</p> <p>24 widely accepted that migration happens. He told</p> <p>25 me that he specifically told the defense counsel</p>
<p style="text-align: right;">Page 239</p> <p>1 review of the case.</p> <p>2 Q. Okay. Did you ever have an opportunity</p> <p>3 to talk to Dr. Scully about talc and ovarian</p> <p>4 cancer?</p> <p>5 A. I believe my conversations were -- my</p> <p>6 memory is -- this is 20 years ago now -- it's</p> <p>7 possible, but probably with Dr. Bell, more. I</p> <p>8 interacted more with Dr. Bell than Dr. Scully.</p> <p>9 Dr. Scully was semiretired at the time. He</p> <p>10 would come in for half the day, but that was</p> <p>11 usually when I was with other attendings. But I</p> <p>12 did spend a significant time with Dr. Bell, and I</p> <p>13 do remember being aware of that literature.</p> <p>14 Now, if you're going to ask me the specific</p> <p>15 conversation, I probably can't prompt that at the</p> <p>16 moment.</p> <p>17 I was also, when I was at Beth Israel</p> <p>18 Deaconess, my colleague Jonathan Hecht is there.</p> <p>19 And I was aware he was doing work on the Nurses'</p> <p>20 Health Study.</p> <p>21 We didn't -- I can't remember if we really</p> <p>22 talked about talc at that point because the Gates</p> <p>23 2010 paper that he was doing, talc was a very</p> <p>24 small -- it was almost, like, a side comment in</p> <p>25 that report. But I think we had talked about --</p>	<p style="text-align: right;">Page 241</p> <p>1 he met with not to use migration because it's</p> <p>2 widely accepted that it occurs.</p> <p>3 We did talk about the Nurses' Health paper.</p> <p>4 He said that the data set was very small, it was</p> <p>5 very difficult with classification, and that</p> <p>6 that -- there just really wasn't a lot of data in</p> <p>7 that 2010 study.</p> <p>8 And he thinks that it is plausible for</p> <p>9 talcum powder to cause ovarian cancer.</p> <p>10 Q. Have you spoken to any other</p> <p>11 pathologist or colleagues about talc and ovarian</p> <p>12 cancer?</p> <p>13 A. I have talked to my coworkers about it</p> <p>14 because -- as a conflict-of-interest notification</p> <p>15 for our group and for our hospital, Partners</p> <p>16 Healthcare, and I discussed my findings with my</p> <p>17 partners.</p> <p>18 And I've also talked about it at</p> <p>19 multidisciplinary conferences; recently at, for</p> <p>20 example, at a thoracic conference. There were</p> <p>21 gyn oncs there and radiologists and rad onc</p> <p>22 people there.</p> <p>23 Q. And you talked to them specifically</p> <p>24 about talc and ovarian cancer?</p> <p>25 A. So I told them about my work on it and</p>

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<p>1 the research that I had done, and I was asking 2 them -- it was a thoracic conference, so I was 3 curious if any of them had asked any of their 4 mesothelioma patients that didn't have 5 nonasbestos exposure if they've ever asked them 6 if they'd had talc exposure. 7 And they said no, they hadn't really done 8 it, they hadn't thought about it, but maybe it 9 was something that they should be asking. 10 Q. And, by the way, what were the 11 circumstances under which you and Dr. Hecht had 12 dinner the other night? 13 A. His birthday is coming up. We're still 14 friends, so it was one of these -- I actually 15 stayed in a hotel last night because it took me 16 an hour and a half to drive from Topsfield 17 yesterday morning, and I didn't want to be 18 worried about traffic. So I decided to stay in a 19 hotel last night. His birthday is coming up, so 20 I said, "Let's just grab a drink." 21 Q. You mentioned while you were at Mass 22 General, the fellowship director for your program 23 was Robert Young; correct? 24 A. Yes. 25 Q. Is he someone that you look up to as a</p>	<p>1 Dr. Scully retired; is that right? 2 A. Yes. He inherited his consult service. 3 So it's a separate service from our regular 4 clinical work. So it's pathologists from all 5 over the country or even world that have 6 difficult cases, they will send as a specific 7 private consult to -- it was Dr. Scully, and now 8 it's Dr. Young. 9 Q. Okay. When you were first contacted by 10 the plaintiffs' counsel back in 2017, what were 11 your opinions regarding talc and ovarian cancer 12 at that point? 13 A. First contacted? When I was first 14 contacted, I was aware of the literature, 15 certainly. I hadn't come to a strong opinion one 16 way or the other. In fact, I'd probably say I 17 was aware that the epi data had been relatively 18 consistent. That was kind of all I knew about it 19 until I did my sort of deep dive into the 20 literature for my general causation opinion. 21 Q. So as a pathologist, you never had a 22 particular interest in pursuing additional 23 research in the area -- 24 MR. ROTMAN: Objection. 25 Q. -- of talc and ovarian cancer?</p>
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<p>1 pathologist? 2 A. Yes. He's very well-respected. 3 Q. By the way, who do you send second 4 opinion consults to when you have a difficult 5 case? 6 A. We have a relationship with Mass 7 General, so I'll occasionally send -- if I need 8 another set of eyes on, I'll send it to either -- 9 it's sort of their gyn pathology group in 10 general, so it might be Dr. Young. It might be 11 Esther Oliva. Those are the two that I would say 12 most frequently would receive any consults from 13 our group for gyn path. 14 Q. Have you ever spoken with Dr. Young 15 about talc and ovarian cancer? 16 A. It's possible. I haven't recently. He 17 and I aren't in regular communication, so I 18 certainly wouldn't have talked to him -- I don't 19 know if I've talked to him since starting this. 20 It's more of a professional-type 21 relationship, so I don't know if it would have 22 come up recently. But it's possible in training, 23 but I don't remember specifically. 24 Q. And Robin Young inherited all of 25 Dr. Scully's case files in his office when</p>	<p>1 A. Well, there's certainly a lot of things 2 to study in gynecologic pathology. And so I 3 hadn't decided to take that -- to do that study 4 at the time that I was contacted by counsel. 5 That's not to say I never would have or I never 6 would have thought about it, but I hadn't at the 7 time. 8 Q. Okay. In your report on Page 4, you 9 say that you've maintained a professional 10 interest -- "since your fellowship, you've 11 maintained a professional interest and have 12 continued to monitor developments in the science 13 regarding talcum powder exposure and ovarian 14 cancer, and it has been the subject of 15 professional discussions predating the 16 litigation." 17 So what sort of professional discussions 18 about talc and ovarian cancer did you have before 19 the plaintiffs retained you? 20 A. So, again, I was aware of the 21 literature. And I knew -- I saw some of the 22 newer epi data come out. I had had conversations 23 with Dr. Bell that I remember specifically; 24 again, with Jonathan. I knew he was working on 25 that Nurses' Health. We certainly talked about</p>

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<p>1 that study at some point.</p> <p>2 But, you know, I was certainly aware of the</p> <p>3 literature as it came out.</p> <p>4 Q. And you call it a "professional</p> <p>5 interest."</p> <p>6 Did you take -- other than just reviewing</p> <p>7 the literature, did you do anything</p> <p>8 professionally to either advance your knowledge</p> <p>9 or other people's knowledge about this potential</p> <p>10 association?</p> <p>11 A. Not -- I mean, not at the time. I</p> <p>12 think "professional interest" in my mind, you</p> <p>13 know, means being aware of what's going on in the</p> <p>14 literature. Again, that doesn't necessarily mean</p> <p>15 an in-depth review of everything but being</p> <p>16 generally aware of it.</p> <p>17 Q. Would you say that since you first</p> <p>18 learned about this in your fellowship and were</p> <p>19 interested in the topic, did it influence the way</p> <p>20 you looked at gynecologic cases as a professional</p> <p>21 pathologist?</p> <p>22 A. Yeah. It's not really routine practice</p> <p>23 to use polarized light microscopy in gynecologic</p> <p>24 pathology. It's just -- we use it more commonly</p> <p>25 for breast cases, so...</p>	<p>1 in the report.</p> <p>2 Q. Okay. And the first opinion is that</p> <p>3 talc can migrate to the ovaries through the</p> <p>4 genital tract through the lymphatic system and</p> <p>5 through inhalation.</p> <p>6 Is that an accurate summary of your first</p> <p>7 opinion or set of opinions?</p> <p>8 (reading from document)</p> <p>9 A. Yes. The talcum powder products can</p> <p>10 reach the ovaries; that they can be transported</p> <p>11 through the lymphatic system; and there is</p> <p>12 evidence that it can be inhaled as well with</p> <p>13 transport to the ovaries.</p> <p>14 Q. And the second opinion in the case or</p> <p>15 second set of opinions is that talc causes</p> <p>16 chronic inflammation in the ovaries, causes</p> <p>17 increased oxidative stress in the ovaries, and</p> <p>18 causes immunosuppression.</p> <p>19 Is that an accurate summary of your</p> <p>20 mechanism?</p> <p>21 A. Well, if you're going to read it word</p> <p>22 for word, it's "Once reaching the ovaries, talcum</p> <p>23 powder products can cause chronic inflammation,</p> <p>24 can increase oxidative stress, and can reduce</p> <p>25 immune response. These are biologically</p>
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<p>1 And also, you know, even if we found</p> <p>2 birefringent particles and granulomas or -- in</p> <p>3 the tissue, it wouldn't necessarily mean that</p> <p>4 they're talc unless you do subsequent studies.</p> <p>5 So I wouldn't say it changed my daily</p> <p>6 practice in diagnosing tumors.</p> <p>7 Q. Okay. Doctor, if you can turn to</p> <p>8 Page 4 and 5 of your report.</p> <p>9 Is this where you set out a summary of your</p> <p>10 opinions?</p> <p>11 A. Yes. This is.</p> <p>12 Q. Under Heading 2, Page 4, "General</p> <p>13 causation opinions."</p> <p>14 A. Okay.</p> <p>15 Q. And you list, it looks like, five</p> <p>16 specific opinions; is that correct?</p> <p>17 A. I see where you are. Yes.</p> <p>18 Q. And are those -- again, are those all</p> <p>19 the opinions that you have that you intend to</p> <p>20 offer in this case?</p> <p>21 MR. ROTMAN: Objection.</p> <p>22 A. Same answer as before. Again, there</p> <p>23 might be something that comes up today or at</p> <p>24 trial that I'm asked that I, you know, didn't put</p> <p>25 in this report. But I tried to be as -- complete</p>	<p>1 plausible and likely mechanisms for ovarian</p> <p>2 cancer development and progression."</p> <p>3 Q. Okay. When you say "reduce the immune</p> <p>4 response," is that essentially discussing, like,</p> <p>5 an immunosuppressive effect?</p> <p>6 A. That's referencing the MUC-1 antibody</p> <p>7 paper that Cramer published in 2005.</p> <p>8 Q. Are you aware that Dr. Cramer himself</p> <p>9 has disclaimed that theory as a "hypothesis</p> <p>10 that's not ready for prime time"? I believe</p> <p>11 those were his words, "prime time."</p> <p>12 A. I don't know where you saw those words.</p> <p>13 Q. His testimony in the litigation.</p> <p>14 A. Okay. I don't believe I saw his</p> <p>15 testimony in the litigation. But, again, it's</p> <p>16 not -- I'm not seeing it as something that needs</p> <p>17 to be proven. I'm looking at it as a</p> <p>18 plausibility that, you know, it's a plausible</p> <p>19 mechanism. If it's not proven, it doesn't really</p> <p>20 change the fact that it's plausible.</p> <p>21 Q. So are you building -- so is your</p> <p>22 plausibility opinion independent of whether or</p> <p>23 not the basis for that opinion is proven?</p> <p>24 MR. ROTMAN: Objection.</p> <p>25 Q. In other words, are you -- do you have</p>

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<p style="text-align: right;">Page 250</p> <p>1 a plausibility opinion that's based on a bunch of 2 other potential or plausible mechanisms? 3 MR. ROTMAN: Objection. 4 A. Right. 5 MR. ROTMAN: I just objected, but you 6 can answer. If you can understand the question, 7 you can answer it. 8 A. Well, I think -- I think they're all 9 somewhat interrelated. 10 I think there's the chronic inflammation. 11 There's the immune response. Those are plausible 12 mechanisms for ovarian cancer. 13 And the Bradford Hill guidelines, you don't 14 have to prove -- prove mechanism in order to have 15 causation. We have plenty of -- again, plenty of 16 examples of that in prior diseases, like smoking 17 and lung cancer. And even certain drugs, they 18 don't know the mechanism of action, very common 19 drugs like lithium, for example, or metformin. 20 So you don't need to prove mechanism in 21 order for it to be an important part of a 22 causation because it's part of the plausibility 23 component. 24 Q. Do any of the bases on which you -- any 25 of the bases that you use to support plausibility</p>	<p style="text-align: right;">Page 252</p> <p>1 reaching the ovaries. 2 So -- and, again, it's widely accepted in 3 the gynecologic community that migration occurs. 4 In fact, endometriosis, we really -- the evidence 5 is that endometriosis is caused by retrograde 6 menstruation of endometrium. 7 So there's a substantial amount of evidence 8 and widely accepted that migration occurs. 9 And I'm aware of studies that didn't find 10 migration, but I think, you know, those few 11 negative studies don't cancel out the positive 12 studies. 13 And, you know, certainly, looking for 14 migrated particles is very difficult. You know, 15 again, we're talking about dose. How much do you 16 inject to get there? 17 And so I think the positive studies are 18 compelling, and it's widely accepted that 19 migration occurs. 20 (Article entitled "Presence of 21 Talc in Pelvic Lymph Nodes of a Woman with 22 Ovarian Cancer and Long-Term Genital 23 Exposure to Cosmetic Talc" marked Exhibit 24 19.) 25</p>
<p style="text-align: right;">Page 251</p> <p>1 for talc and ovarian cancer, do any of them have 2 to be proven or established? 3 MR. ROTMAN: Objection. 4 A. I think it's important to have evidence 5 to support it. There may be evidence that 6 refutes it as well, but you're sort of looking 7 at -- you're balancing the weight of it. 8 And the plausibility, a plausible mechanism, 9 now, is that always going to be probable or 10 definite? No. It's plausible. 11 In this case, I think it's a compelling 12 mechanism, chronic inflammation, because, again, 13 we know that talcum powder can reach the ovaries, 14 and we know that it can cause chronic 15 inflammation, and we know chronic inflammation is 16 implicated in cancer. 17 So I think it's a high degree of 18 plausibility in that case. 19 Q. So when you mention that you know that 20 talc can reach the ovaries, are you referring to, 21 for example, the Heller study? 22 A. So Heller found talc in women's 23 ovaries. Yes. Cramer found talc in pelvic lymph 24 nodes. We have other animal and human studies of 25 talc or particulates similar in size to talc</p>	<p style="text-align: right;">Page 253</p> <p>1 BY MS. AHERN: 2 Q. Doctor, I'm handing you what's been 3 marked as Exhibit 19 to your deposition. 4 A. Okay. 5 MR. TISI: Thank you. 6 MS. AHERN: You're welcome. 7 Q. Exhibit 19 is an article drafted by 8 Dr. Dan Cramer, the "Presence of talc in pelvic 9 lymph nodes of a woman with ovarian cancer and 10 long-term genital exposure to cosmetic talc." 11 Is this a paper that you were referring to a 12 few minutes ago? 13 A. The 2005, yes. 14 Q. This is 2007. 15 A. I'm sorry. Did I say 2005? Yes. This 16 is the paper, anyway. 17 Q. And the authors are Dan Cramer and Bill 18 Welch, Ross Berkowitz, and John Godleski. 19 Do you see that? 20 A. Yes. 21 Q. And three of those individuals have 22 been disclosed as plaintiffs' experts in the talc 23 litigation. 24 Were you aware of that? 25 A. I was not aware of Bill Welch. I knew</p>

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<p style="text-align: right;">Page 254</p> <p>1 after -- at some point, I was aware that  2 Dr. Cramer and Dr. Godleski was. I don't believe  3 I was aware of that at the beginning of my  4 research, but I became aware of that. Yes.  5 Q. Okay. Are you aware that Dr. Welch has  6 been designated in maybe three cases and given  7 testimony in those cases?  8 A. Again, I was not aware that Bill Welch  9 had been retained.  10 Q. Are you aware that Dr. Welch has run  11 the pathology portion of Dr. Cramer's study  12 program for 40 years?  13 A. I'm aware who Dr. Welch is, and I've  14 certainly seen his name on papers. But now  15 his -- his role in these studies specifically, I  16 don't know if I can speak to other than he's  17 involved.  18 Q. He's testified that his only role was  19 in identifying the types of tumors involved in  20 the study to keep people honest.  21 Are you aware that Dr. Welch has repeatedly  22 refused to give -- refused to give a causation  23 opinion like you're giving today?  24 A. I'm not aware of Dr. Welch's opinions.  25 I didn't know that he was an expert, so I</p>	<p style="text-align: right;">Page 256</p> <p>1 A. I'm sorry. Where are you now?  2 Q. Same sentence. He just finishes it  3 with "Many subsequent studies found --  4 A. Okay.  5 Q. -- "talc use to increase the risk for  6 ovarian cancer."  7 But he just cites himself again from 1982;  8 correct?  9 A. Sorry?  10 Q. The only cite he provides for that  11 statement is his own study from 1982?  12 A. Oh, the one -- the No. 1?  13 Q. Mm-hmm.  14 A. Yes. That's his 1999, it says. 1999.  15 Q. Okay. Sorry about that. You're right.  16 And then he says, "However, the causality of  17 the relationship has been challenged for several  18 reasons."  19 Do you see that?  20 A. I do.  21 Q. And he says, "First, the association is  22 a relatively weak one; i.e., summary relative  23 risk of approximately 1.3."  24 Do you agree that a summary relative risk of  25 1.3 is a weak association?</p>
<p style="text-align: right;">Page 255</p> <p>1 wouldn't have reviewed any of that testimony.  2 Q. Okay. You weren't provided with any of  3 his testimony or his reports in the litigation?  4 A. No. I was not aware that he was a  5 medical expert witness.  6 Q. Okay. Do you see under the  7 "Background" section here, it says, "Although  8 epidemiologic studies suggest talc may increase  9 ovarian cancer risk, there is no proof that talc  10 used externally reaches the pelvis"?  11 A. That's what it says.  12 Q. Are then if you look down in the -- I'm  13 sorry. I'm sorry.  14 If you look down in the first paragraph, he  15 mentions, "An epidemiologic association between  16 the use of cosmetic talc and genital hygiene and  17 ovarian cancer was first described in 1982."  18 That's Cramer citing Cramer; isn't it?  19 A. Let's see. Let me double-check. I'm  20 assuming because it's 1982. But let me  21 double-check. Or -- yeah. It's 1999. He's  22 referencing his 1999 paper.  23 Q. And he says, "And the many subsequent  24 studies found talc use to increase the risk for  25 ovarian cancer."</p>	<p style="text-align: right;">Page 257</p> <p>1 A. I've seen "weak" or "moderate" used to  2 describe a 1.3, but that doesn't mean it's not a  3 significant one, especially in a rare disease  4 like ovarian cancer.  5 MS. AHERN: Objection to the  6 nonresponsive portion.  7 Q. But I agree it's been described as  8 "weak," at least here by Dr. Cramer?  9 A. That's -- the sentence says, "First,  10 the association is a relatively weak one; i.e.,  11 summary relative risk of approximately 1.3."  12 Q. And he says, "Second, there's no clear  13 increase in risk with duration of use."  14 Do you agree with that, as of 2007, there  15 was no clear dose-response in the studies that  16 looked at talc and ovarian cancer?  17 A. I think there was evidence of a  18 dose-response by 2007.  19 Q. So do you disagree with Dr. Cramer's  20 statement in the 2007 publication that as of that  21 time, there was no clear increase in risk with  22 duration of use in most studies?  23 A. I wouldn't necessarily phrase it that  24 way: There's no clear increased risk. I think,  25 again, there isn't a lot of data, but what data</p>

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<p>1 there was -- I believe at that time, I'm trying 2 to think if I was in 2007 -- would be evidence 3 that there was a dose-response. 4 Q. And which papers, prior to 2007, did 5 they find dose-response that was clear? 6 A. I would have to look back. 7 Okay. So I tried to do this in chronologic 8 order. 9 Q. What page are you on? 10 A. I'm looking at 16. 11 Q. Page 16 of Exhibit 14? 12 A. Yes. 13 Q. Okay. Were -- 14 A. I'm just trying to refresh my memory. 15 So Harlow's -- let's see -- 1992 study was, 16 it looks like, the first one that I have listed 17 that had a dose-response -- evaluated for 18 dose-response. 19 They both -- let's see. The confidence 20 intervals all included the null. Life- -- so 21 what I wrote here -- this is Page 18 -- "lifetime 22 application ORs when compared to control women 23 with no perineal talc exposure were 1.3, 4 less 24 than 1,000, with a confidence interval of 0.7 to 25 2.7; 1.5 for 1,000 to 10,000 with a confidence</p>	<p>1 2.4. 2 And for greater than 10,000, we're looking 3 at 1.0 to 3.0. 4 Q. And when they just adjusted -- when 5 they excluded -- when they looked at lifetime 6 talc applications and ovarian cancer after 7 excluding use following hysterectomy or tubal 8 ligation, they found no evidence of an 9 exposure-response relationship, didn't they? 10 A. Are you looking at the actual paper? 11 Q. Do you need it? 12 A. If you're asking me questions about it. 13 Q. Yeah. That wasn't in your report -- or 14 is it? 15 MR. ROTMAN: What is the "it" referring 16 to? 17 Q. That particular finding is not in her 18 report on dose-response from Harlow in 1992? 19 A. Well, yeah. Let me look at the -- 20 MS. AHERN: Sure. 21 (Article entitled "Perineal 22 Exposure to Talc and Ovarian Cancer Risk" 23 marked Exhibit 20.) 24 MS. AHERN: I'll mark as Exhibit 20 to 25 your deposition "Perineal Exposure to Talc and</p>
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<p>1 interval of 0.9 to 2.4; and 1.8 for greater than 2 10,000 with the confidence interval of 1.0 to 3 3.0. 4 And then I also -- yeah. So that's after 5 2007, the Terry and the Lou studies. 6 Q. You're looking at Harlow 1992? 7 A. Yes. That's the paragraph I'm looking 8 at. 9 Q. And Harlow 1992 found a 10 nonstatistically significant increased risk; is 11 that correct? 12 A. So the confidence intervals included 13 the null. So, yeah, it was not statistically 14 significant. I'm not sure -- I don't have the 15 numbers here, though, of how many they had 16 dose-response data on, which would -- which might 17 increase the interval. 18 In fact, if you look at the confidence 19 intervals, they're pretty wide, trending toward 20 higher. 21 Q. What are the confidence intervals 22 you're looking at? 23 A. For less than 1,000 lifetime 24 applications, we're looking at 0.7 to 2.7. 25 For 1,000 to 10,000, we're looking at 0.9 to</p>	<p>1 Ovarian Cancer Risk" by Harlow, 1992. That's my 2 only copy. Sorry. 3 MR. ROTMAN: Exhibit 20. 4 A. Okay. So, I'm sorry, where are you 5 looking? 6 Q. Let me find it. Take your time, if you 7 need to. I'm trying to find my copy. 8 Okay. If you look at Table 3, "Estimated 9 total lifetime perineal applications of talc 10 containing powders and cases and controls." 11 A. Okay. I see Table 3. 12 MR. ROTMAN: Is there a question? 13 MS. AHERN: She asked to see the study. 14 I asked her to confirm that once they excluded 15 cases after hysterectomy or tubal ligation, there 16 was no exposure-response relationship. 17 A. These look to be similar -- oh, I see. 18 Okay. Total applications. 19 Well, if you actually look at the numbers, 20 the ones above, which are, I believe, what I 21 quoted in my report, so under "Total 22 applications." 23 And then you're asking me about applications 24 excluding use after hysterectomy or tubal 25 ligation?</p>

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<p style="text-align: right;">Page 262</p> <p>1 BY MS. AHERN: 2 Q. Mm-hmm. 3 A. What was your question about it? I'm 4 sorry. 5 Q. There's no statistically significant 6 dose-response relationship with lifetime 7 application? 8 A. So the confidence intervals are 9 somewhat similar, but -- are somewhat similar, it 10 looks like, to the top. 11 Q. There's no statistically significant 12 dose-response relationship, is there? 13 A. They all include the null. That's 14 correct. But, again, they're trending high. 15 Q. But if they include the null, then it's 16 consistent with the null hypothesis that there's 17 no association; isn't that true? 18 MR. ROTMAN: Objection. 19 A. It's possible. The null hypothesis is 20 included in "Possibilities." 21 Q. It also basically means you can't 22 exclude chance as a reason for the findings; 23 correct? 24 A. Again, it's possible. I would say it's 25 trending higher, but it does include the null</p>	<p style="text-align: right;">Page 264</p> <p>1 dose-response? 2 A. Well, I state in my report what the 3 confidence intervals are. So certainly, I'm 4 showing that it did include the null hypothesis. 5 But I think it's still -- just because it's not 6 statistically significant, I think it's still 7 data, and I wouldn't completely discount it. 8 But it does -- does contain the null. The 9 numbers weren't super high, if I remember. But 10 on their -- I'll have to find it. 11 On -- in their abstract conclusion, they 12 still say that "The greatest ovarian cancer risk 13 associated with perineal talc use was observed in 14 the subgroup of women estimated to have made more 15 than 10,000 applications during years when they 16 were ovulating and had an intact genital tract 17 with the OR of 2.8 and a statistically 18 significant confidence interval of 1.4 to 5.4. 19 However, this exposure was found in only 20 14 percent of the women with ovarian cancer." 21 Q. Okay. But we were just asking -- you 22 mentioned the study as support for a 23 dose-response relationship in your report? 24 A. As evidence of a dose -- a 25 dose-response; again, with the caveat, which is</p>
<p style="text-align: right;">Page 263</p> <p>1 hypothesis. 2 Q. Do you see on Page 25, in the first 3 column on the left-hand side, the first full 4 paragraph, "In our analysis"? 5 Okay. The authors say, "In our analysis, we 6 first calculated all genital applications of talc 7 based on frequency and years of use. As a 8 continuous variable in a multivariate model, no 9 significant dose-response was observed between 10 total genital applications of talc and ovarian 11 cancer risk"; correct? 12 A. That's what it says. 13 Q. And the reason they excluded 14 hysterectomy and tubal ligation is the next 15 sentence, "because the translocation theory 16 assumes an open genital tract, we then excluded 17 application after tubal ligation or hysterectomy 18 but observed no appreciable change in the 19 dose-response." 20 In other words, still no significant 21 dose-response; correct? 22 A. That's what it says. 23 Q. So the authors interpreted both the 24 data you cite in your report as well as the data 25 you didn't cite in your report as showing no</p>	<p style="text-align: right;">Page 265</p> <p>1 here, that it includes the null hypothesis. 2 Q. Okay. And what about Cramer in 1999? 3 MR. ROTMAN: Objection. I don't think 4 that's a question. 5 MS. AHERN: Fair point. 6 BY MS. AHERN: 7 Q. In Cramer 1999, you've also cited as 8 evidence after dose-response, correct, on Page 35 9 of your report? 10 A. I see that. Yes. It's listed in a 11 reference list. 12 Q. And the authors, including Cramer, 13 basically say they "failed to demonstrate 14 consistent dose-response relationships with 15 measures of intensity of exposure." 16 MR. ROTMAN: Do you have -- do you have 17 the paper? 18 MS. AHERN: Do you want the paper? 19 MR. TISI: Is that the one you 20 identified before? 21 MS. AHERN: No. This is a new one. 22 MR. ROTMAN: She's getting the paper 23 out. 24 MS. AHERN: I thought I had it too. 25 Maybe it's in one of the boxes. Let me see if I</p>

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<p style="text-align: right;">Page 266</p> <p>1 can find my own copy.  2 Okay. Sorry. This is the only copy I  3 have right now.  4 THE WITNESS: Okay.  5 MS. AHERN: We can mark it, if you  6 want.  7 BY MS. AHERN:  8 Q. It's a copy of the Cramer 1999  9 publication that you cited in your report in  10 support of dose-response.  11 MR. TISI: Are you marking it?  12 THE COURT: I can if you want me to. I  13 just didn't want to mark my copy.  14 MR. KLATT: I don't think I do.  15 MS. AHERN: That's all right. I don't.  16 We'll mark Cramer -- oops, no, we won't because  17 this is the wrong study. Sorry. The old "wrong  18 study" trick.  19 THE WITNESS: I can't find that  20 information. Oh, I've got the wrong reference.  21 Sorry. All righty.  22 (Article entitled "Genital Talc  23 Exposure and Risk of Ovarian Cancer" marked  24 Exhibit 21.)  25</p>	<p style="text-align: right;">Page 268</p> <p>1 in the table. Let me see.  2 Q. I think so. If you want to go to --  3 A. Oh.  4 Q. You got it.  5 A. Yes. I see it now. Sorry. It was  6 buried in Table 3, very small print. Okay. Yes.  7 So Table 3, years of use. Yup.  8 Q. Do you see they're not showing a  9 statistically significant dose-response  10 relationship?  11 A. So for less than 20 years, the  12 confidence intervals were 1.16 to 3; at 20 and 30  13 and greater than 30, they did -- the confidence  14 intervals did include the null.  15 But, again, I don't know how many -- I can't  16 remember. Oh, here are the cases.  17 Yeah. So there are 55, less than 20 cases;  18 thirty-two 20 to 30; and 59 greater than 30.  19 Q. And you see also the frequency  20 analysis? It also did not find a significant  21 dose-response relationship as a statistically  22 significant dose-response relationship?  23 A. Yes. For less than 30 years, the  24 adjusted OR was 2.21 with a confidence interval  25 of 1.37 to 3.56.</p>
<p style="text-align: right;">Page 267</p> <p>1 BY MS. AHERN:  2 Q. Okay. So, Doctor, this is Exhibit 21,  3 which is "Genital Talc Exposure and Risk of  4 Ovarian Cancer," Dan Cramer, 1999.  5 A. Okay.  6 Q. This is something else.  7 Can you find -- I don't have it in front of  8 me, so I'm going to rely on you to find the  9 tables that show their dose-response analysis.  10 MR. ROTMAN: You made that Exhibit 21?  11 MS. AHERN: Yes.  12 MR. TISI: It's 21. Yes.  13 THE WITNESS: Would that be Table 2,  14 what you're referring to (indicating)?  15 BY MS. AHERN:  16 Q. I believe the numbers were -- they were  17 looked at in terms of zero years' duration, less  18 than 20, 20 to 30, and greater than 30.  19 Do you see that on there?  20 A. I'm looking. This one says "less  21 than -- frequency of use."  22 Q. There's a frequency and a duration.  23 A. Okay.  24 Q. Yeah.  25 A. Sorry. Why am I not seeing it? It's</p>	<p style="text-align: right;">Page 269</p> <p>1 The 30 to 39 was adjusted OR of 1.17 with  2 confidence intervals .78 to 1.76.  3 And the 40-plus adjusted OR was 1.57 with  4 confidence intervals of 0.8 to 3.10.  5 Q. So not only did the point estimate go  6 down with more use, but the higher the  7 concentration, there was also no statistical  8 significance; correct?  9 A. Yeah. I mean, the numbers -- so the  10 only one that doesn't include the null -- let me  11 just double-check.  12 Actually, there are two. So the less than  13 20 years or less than 30 per month are  14 statistically significant.  15 Q. It's only the first dose category in  16 each group --  17 A. Yeah.  18 Q. -- shows statistical significance.  19 And as the doses got higher, the exposure  20 frequency got higher, the point estimates went  21 down and statistical significance went away;  22 correct?  23 A. The confidence intervals did include  24 the null. And I think this illustrates how  25 difficult sort of dose and frequency can be to</p>

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<p style="text-align: right;">Page 270</p> <p>1 study because we don't really know what the doses 2 are, and we don't really have granularity as far 3 as frequency of use. Well, I have to look at -- 4 Q. These are studies that you cited in 5 your report as evidence of a dose-response, 6 correct, the Harlow and the Cramer papers? You 7 both cited yourself. 8 Did you evaluate the internal validity of 9 those studies and critically evaluate the methods 10 and study populations when you included them in 11 your report? 12 A. Let me -- well, I said -- this is the 13 sentence -- "Most have found an increased risk of 14 ovarian cancer with increased exposure." So, 15 yet, when studies have evaluated duration of 16 frequency of perineal talc use. 17 So this list is the studies that evaluated 18 duration and frequency of perineal talc use. And 19 I said, "Most have found an increased risk." So 20 what I'm citing here are the studies that looked 21 at duration and frequency. 22 Q. Okay. And we were referring to 23 Cramer's 2007 publication where he himself says 24 that the association has been challenged because 25 it's weak and because there's no clear increase</p>	<p style="text-align: right;">Page 272</p> <p>1 "application of talc." 2 "Another factor that may affect the 3 dose-response relationship is whether use 4 occurred at a time when the female tract was 5 open. There is evidence from several studies 6 that the talc/ovarian cancer association is 7 modified by closure of the female tract as a 8 result of tubal ligation or hysterectomy. 9 Q. Doctor, did they say they didn't find a 10 dose-response relationship? 11 A. I'm trying to find what they said other 12 than that on Page 355. 13 Yeah. They said, "Studies that have 14 dose-response, including this one, have failed to 15 demonstrate consistent dose-response 16 relationships." 17 But it goes on to qualify with the 18 difficulty of measuring dose and frequency, which 19 is what I described earlier. 20 Q. Mm-hmm. 21 (Article entitled "Perineal Talc 22 Exposure and Epithelial Ovarian Cancer Risk 23 in the Central Valley of California" marked 24 Exhibit 22.) 25</p>
<p style="text-align: right;">Page 271</p> <p>1 in risk with duration of use. 2 And you didn't agree with that statement, 3 and you referred me to Harlow 1992; correct? 4 A. I was going to where I mentioned the 5 dose-response studies. 6 Q. Okay. Just to button up and finish up 7 with Cramer 1999, if you look at Page 355, the 8 authors included, "They failed to demonstrate 9 consistent dose-response relationships with 10 measures of intensity of exposure." 11 Do you see that? 12 A. I'm sorry. Where are you? 13 Q. On Page 355. 14 A. Okay. I'm seeing "in attempting" -- 15 sorry. I see, "Most talc and ovarian cancer 16 studies that have addressed dose-response, 17 including this one, have failed to demonstrate 18 consistent dose-response relationships with 19 measures of the intensity of the exposure, 20 especially when the trend is examined among users 21 only. In attempting to address this weakness, we 22 point out that it is difficult to quantify the 23 amount of powder actually used and degree of 24 perineal dusting that might constitute an 25 application of talc," quote/unquote around</p>	<p style="text-align: right;">Page 273</p> <p>1 BY MS. AHERN: 2 Q. Okay. The next one -- are you done, 3 sorry, with that one? 4 A. If we're moving on, sure. 5 Q. If you're done. 6 The next one you mention, you cite in your 7 report for dose-response is Mills 2004, which I'm 8 handing you now marked as Exhibit 22. 9 Oh, yeah. We'll leave that here for right 10 now. 11 A. Okay. 12 MR. ROTMAN: Can I see the one you just 13 finished with? 14 MR. TISI: This is 22; right? 15 MS. AHERN: Yes, sir. 16 BY MS. AHERN: 17 Q. And this one, you're welcome to read 18 through it if you want. All I wanted to point 19 out is if you look right up front in the 20 abstract, a little more than midway down, they 21 say, "The odds ratio for ever use of talc was 22 1.37 with the confidence interval of 1.02 to 1.85 23 compared to never users. However, no 24 dose-response association was found." 25 Do you see that?</p>

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<p>1 A. I see where it says that.</p> <p>2 Q. And if you want to look through there</p> <p>3 and convince yourself of that, go for it. I</p> <p>4 think the table that we're looking at is Table 2</p> <p>5 on Page 460.</p> <p>6 A. Yeah. The 4 to 12 years had an OR of</p> <p>7 1.86 that was statistically significant at 1.16</p> <p>8 to 2.98. But the others, which were never --</p> <p>9 which, of course, is the null, 4 to 12 years,</p> <p>10 which -- oh, the 13 to 30 was adjusted OR of</p> <p>11 1.45, confidence interval .9 to 2.32.</p> <p>12 And then the greater than 30 years was OR of</p> <p>13 1.22 with confidence interval of .72 and 2.08.</p> <p>14 So the 13 to 30 and the greater than 30 includes</p> <p>15 the null.</p> <p>16 And then if we look at frequency, cumulative</p> <p>17 use, frequency types duration, there was a</p> <p>18 statistically significant increase with second</p> <p>19 quartile and third quartile divisions. But then</p> <p>20 it dropped in the fourth quartile, the highest</p> <p>21 exposure.</p> <p>22 And, you know, again, sort of difficulty in</p> <p>23 measuring this. But you do see an increase in</p> <p>24 the second and third quartile, between the second</p> <p>25 and third, that was statistically significant.</p>	<p>1 Q. I was trying to point you a little bit</p> <p>2 toward this. It's Page 463. There's some</p> <p>3 discussion of it.</p> <p>4 If you look at the third paragraph down, "As</p> <p>5 in other studies, the present study did not find</p> <p>6 a clear dose-response based on duration of use or</p> <p>7 cumulative use."</p> <p>8 And then it says, "Limiting the analysis of</p> <p>9 dose-response to women who reported ever use of</p> <p>10 talc did not affect the results, data not shown.</p> <p>11 The lack of dose-response between talc use and</p> <p>12 epithelial ovarian cancer may be explained by the</p> <p>13 inability to quantify the actual amount of talc</p> <p>14 used per application and the timing of the</p> <p>15 application."</p> <p>16 A. Yeah. So with that caveat.</p> <p>17 Q. Well, the findings are what they are;</p> <p>18 right?</p> <p>19 The findings are no dose-response</p> <p>20 relationship?</p> <p>21 A. The findings are what they are. But,</p> <p>22 again, it's not an easy -- there's not huge</p> <p>23 numbers in these cases.</p> <p>24 And, again, you still don't know from woman</p> <p>25 to woman what one dose is, so there's a ton of</p>
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<p>1 And then --</p> <p>2 Q. But the authors themselves interpret</p> <p>3 their data as no dose-response association;</p> <p>4 correct?</p> <p>5 A. In the abstract, that's what they</p> <p>6 state. I'm trying to figure out what their --</p> <p>7 what they said. They must have said a little bit</p> <p>8 more.</p> <p>9 Q. Doctor, you reviewed this study before;</p> <p>10 right?</p> <p>11 A. I did. Yes.</p> <p>12 Q. Okay.</p> <p>13 A. I'm just refreshing my memory.</p> <p>14 Q. Okay. If you look at Page 463.</p> <p>15 MR. ROTMAN: Are you changing the</p> <p>16 topic?</p> <p>17 MS. AHERN: No. Same topic.</p> <p>18 MR. ROTMAN: She was looking for</p> <p>19 something as part of a prior answer.</p> <p>20 BY MS. AHERN:</p> <p>21 Q. As part of your prior answer that there</p> <p>22 was no dose-response?</p> <p>23 A. As part of the answer that they stated</p> <p>24 that in the abstract. I was trying to find out</p> <p>25 where they had a discussion.</p>	<p>1 variability. It's not like a cigarette, where,</p> <p>2 you know, from one cigarette to the next or, you</p> <p>3 know, a drug dose is probably a more accurate</p> <p>4 analogy, you know.</p> <p>5 Q. True. But just because it's difficult</p> <p>6 to study, it doesn't mean if we could study it</p> <p>7 better, we would get a positive result, does it?</p> <p>8 A. I -- oh, my thing is not working. I</p> <p>9 think I have to plug my thing in.</p> <p>10 MR. ROTMAN: Can you?</p> <p>11 COURT REPORTER: I'd have to break to</p> <p>12 do it.</p> <p>13 MR. ROTMAN: Let's go off the record.</p> <p>14 THE VIDEOGRAPHER: Off the record.</p> <p>15 4:37 p.m.</p> <p>16 (A recess was taken.)</p> <p>17 THE VIDEOGRAPHER: Back on the record,</p> <p>18 4:44 p.m.</p> <p>19 BY MS. AHERN:</p> <p>20 Q. Okay. Doctor, you saw the Mills paper</p> <p>21 in front of you?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. Could you look at your report on</p> <p>24 Page 21?</p> <p>25 (Witness complies.)</p>

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<p style="text-align: right;">Page 278</p> <p>1 A. Okay.</p> <p>2 Q. Let's see, where is my copy?</p> <p>3 And turn to Page 3 of the Mills publication.</p> <p>4 A. Page 3, which would be Page 460?</p> <p>5 Q. That's a good question.</p> <p>6 Where is my Mills publication?</p> <p>7 MS. AHERN: Do you have it?</p> <p>8 MR. TISI: Sure.</p> <p>9 MS. AHERN: Thank you.</p> <p>10 Oh, I know where it is.</p> <p>11 BY MS. AHERN:</p> <p>12 Q. I'm sorry. I thought I had the</p> <p>13 specific passage marked. And I do, somewhere in</p> <p>14 here. Okay. Sorry. It's on Page 460. I</p> <p>15 apologize.</p> <p>16 A. Okay.</p> <p>17 Q. All right. Do you see on the Mills</p> <p>18 publication on Page 460 that bottom paragraph on</p> <p>19 the left, "ever use of talcum powder"?</p> <p>20 A. Yes.</p> <p>21 Q. And if you read down toward the bottom</p> <p>22 part of that paragraph, on the fourth line from</p> <p>23 the bottom, the sentence starts "Duration of</p> <p>24 use."</p> <p>25 A. Okay.</p>	<p style="text-align: right;">Page 280</p> <p>1 Q. Is there a reason that that entire</p> <p>2 portion of your report is copied identically from</p> <p>3 Mills except for the qualifier that the pattern</p> <p>4 was not clear-cut for dose-response?</p> <p>5 A. Well, I think it still has the same</p> <p>6 meaning.</p> <p>7 Q. Without the qualifier?</p> <p>8 A. I think the qualifier is in the -- in</p> <p>9 the data.</p> <p>10 Q. Okay.</p> <p>11 A. I don't think I was -- I wasn't trying</p> <p>12 to make it sound anything different than what it</p> <p>13 was. I think I was trying to report the data.</p> <p>14 Q. Okay. All right. And, Doctor, if you</p> <p>15 turn to Page 10 of your report, the section on</p> <p>16 inflammation.</p> <p>17 Are you there?</p> <p>18 A. Yes.</p> <p>19 Q. You start on the second paragraph under</p> <p>20 "Inflammation" discussing oxidative stress.</p> <p>21 A. Okay.</p> <p>22 Q. Okay. Were you aware that a</p> <p>23 significant amount of the section of your report</p> <p>24 on oxidative stress is copied verbatim? More</p> <p>25 than 60 percent of it, I think, is copied</p>
<p style="text-align: right;">Page 279</p> <p>1 Q. "Duration of use of talcum powder was</p> <p>2 associated with increased risk, although the</p> <p>3 pattern was also not clear-cut in that the point</p> <p>4 estimate peaked among those reporting 4 to 12</p> <p>5 years of use and declined somewhat among those</p> <p>6 reporting longer duration of use."</p> <p>7 Do you see that statement?</p> <p>8 A. I see that. Yup.</p> <p>9 Q. And if you look at your report on</p> <p>10 Page 21, the top paragraph, about midway, a</p> <p>11 little -- well, a third of the way down, you pick</p> <p>12 up with "Duration of use of talc was also</p> <p>13 associated with increased risk, although the risk</p> <p>14 peaked."</p> <p>15 Do you see that statement?</p> <p>16 A. Yes.</p> <p>17 Q. If you compare those statements, are</p> <p>18 they almost identical with the exception of the</p> <p>19 statement by Mills that the pattern was not</p> <p>20 clear-cut?</p> <p>21 A. They are similar. This might have</p> <p>22 been, like I described earlier, where, if I was</p> <p>23 taking notes, some of the language might have</p> <p>24 gotten incorporated, although I do have the</p> <p>25 citation.</p>	<p style="text-align: right;">Page 281</p> <p>1 verbatim from Dr. Saed's 2018 publication?</p> <p>2 A. Again, if the language is similar, it</p> <p>3 was not an intentional. I am citing him here, so</p> <p>4 it's -- you know, it's clear that those are the</p> <p>5 references. Again, it might have been due to</p> <p>6 note-taking, but the citation is clear.</p> <p>7 Q. Do you ever take verbatim language out</p> <p>8 of another scientist's work and not set it off in</p> <p>9 quotation marks in your professional work?</p> <p>10 A. I think I've cited the source here.</p> <p>11 It's -- so it's not -- again, it's not like I was</p> <p>12 intentionally copying his words. It was, again,</p> <p>13 probably an editing while I was taking notes, but</p> <p>14 the citations are clear.</p> <p>15 Q. Is your -- is the underlying</p> <p>16 understanding that you have related to oxidative</p> <p>17 stress and inflammation drawn primarily from</p> <p>18 Dr. Saed's work?</p> <p>19 A. No. I mean, oxidative stress and</p> <p>20 inflammation is something that we study -- that</p> <p>21 I've studied.</p> <p>22 Q. Have you ever published a study on</p> <p>23 oxidative stress or redox biology?</p> <p>24 A. I have not published on oxidative</p> <p>25 stress.</p>

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<p style="text-align: right;">Page 282</p> <p>1 Q. What sort of work as a pathologist have 2 you done that incorporates redox biology? 3 A. Well, again, this is part of our 4 medical training. Certainly in training to be a 5 physician, that is something that we learn. And, 6 you know, pathologists do quite frequently come 7 across inflammatory -- inflammation literature. 8 Q. Are you -- is it your position that the 9 information in your report under "Inflammation" 10 that discusses oxidative stress and redox biology 11 is common knowledge among pathologists? 12 A. That oxidative stress and inflammation, 13 yes. I think -- yes. I think that's widely 14 accepted. 15 Q. The specific information contained on 16 Pages 10 and 11 of your report that was drawn 17 from Dr. Saed's work, is that information that is 18 common knowledge? 19 The specific enzymes that are discussed, the 20 research on these issues, is that specific 21 information there common knowledge? 22 A. It's common knowledge that these types 23 of cancer are associated with inflammation, and 24 certainly oxidative stress is part of 25 inflammation.</p>	<p style="text-align: right;">Page 284</p> <p>1 A. I did attribute -- I certainly cited 2 him in several places in this area. And, again, 3 it was not an intentional copying. Again, it 4 might have just happened with my editing, but I 5 certainly tried to cite everything that I was 6 looking at in the proper place. 7 But I do believe that it's common knowledge 8 that chronic inflammation can cause different 9 types of cancer. This is not really new data. 10 Q. Dr. Saed says that it's new data. 11 A. In what respect, though? If we're 12 talking about myeloperoxidase, yes. But I'm 13 talking about oxidative stress and chronic 14 inflammation with known association with certain 15 types of cancer. 16 Q. So it's your testimony that the 17 verbatim text that you used in the section from 18 Dr. Saed's 2018 paper was appropriately cited and 19 attributed to him? 20 MR. ROTMAN: Objection. 21 A. Again, I'm not sure it's absolutely 22 verbatim, but I certainly cited him in every 23 place that I was referencing. 24 Q. Okay. We'll just move on. 25 (Highlighted copy of Dr. Kane's</p>
<p style="text-align: right;">Page 283</p> <p>1 Q. Was this common knowledge to you before 2 you reviewed Dr. Saed's 2018 publication? 3 A. Yes. I was just citing his report at 4 this point. 5 Q. Are you aware you also cited his 6 underlying citations in the same spots that he 7 cited them? 8 A. That's possible because I reviewed his 9 citations as I was reading his citations. 10 Q. Did Dr. Saed give you permission to 11 copy his -- the language from his publication? 12 A. I wouldn't characterize it as 13 "copying." I think it may be similar language, 14 again, because I was writing as I was reading. 15 But I am certainly clearly citing his work and 16 the other citations. 17 Q. Do you agree that Dr. Saed's 2018 18 paper is a compilation of his own synthesis and 19 review of the underlying articles that he 20 incorporated into his paper, and do you think 21 it's appropriate for you to just lift the 22 language from his paper and the citations that he 23 found and synthesized and put it in your report 24 and not attribute it to him with quotation marks? 25 MR. ROTMAN: Objection.</p>	<p style="text-align: right;">Page 285</p> <p>1 expert report marked Exhibit 23.) 2 BY MS. AHERN: 3 Q. Doctor, I've marked as Exhibit 23 to 4 your deposition a highlighted copy of your report 5 that shows the verbatim text that has been 6 carried over from various publications into your 7 report. 8 If you turn to Page 10 and 11, you'll see 9 that the highlighted portions are copied directly 10 from Dr. Saed's work. 11 MR. ROTMAN: Do you have a copy for me 12 of this exhibit? 13 MS. AHERN: Oh. I do. Sorry about 14 that. 15 MR. ROTMAN: So we're at Page 10 and 16 11? 17 MS. AHERN: That's just for the Saed 18 publication. And there's one in there that Saed 19 was also on. 20 MR. ROTMAN: Does she have the Saed 21 publication in front of her? 22 MS. AHERN: I can find it for you. 23 BY MS. AHERN: 24 Q. But my point is, are you aware that 25 that -- that there's a significant portion of</p>

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<p style="text-align: right;">Page 286</p> <p>1 that section of your report that is just 2 cut-and-pasted from Dr. Saed's work? 3 A. I don't believe -- again, it's -- it 4 wasn't intentional with the citations, and it 5 could have happened with my note-taking or other 6 suggested input. But, again, I cited -- I 7 certainly cited him in that section. 8 Q. Okay. 9 MR. TISI: Did you mark that? 10 MS. AHERN: Hmm? 11 MR. TISI: Did you mark that as an 12 exhibit? 13 MS. AHERN: Yes. I think it's 23. 14 Sorry. 15 MR. TISI: That's okay. 16 MR. ROTMAN: Do you have the Saed in 17 front of you? 18 BY MS. AHERN: 19 Q. I think it's -- it wasn't intentional 20 is your testimony, and it's probably just a 21 result of your note-taking process; is that 22 correct? 23 A. Well, because I cited him specifically, 24 certainly it wasn't intentional to be verbatim. 25 And I'm not sure exactly the process, but</p>	<p style="text-align: right;">Page 288</p> <p>1 biology and inflammation, are you? 2 A. I am not currently participating in a 3 study of oxidative stress or redox biology. 4 Q. You don't have any funding related to 5 oxidative stress and inflammation, do you? 6 A. No, I do not. 7 Q. Have you ever applied for any funding 8 in that area? 9 A. No. I have not. 10 Q. Have you ever authored a systematic 11 review of the literature on oxidative stress and 12 inflammation? 13 A. Oxidative stress and inflammation, no. 14 I don't believe I have. 15 Q. Have you ever authored a systematic 16 review of the literature on oxidative stress and 17 cancer? 18 A. No. I have not authored a systematic 19 review on that. 20 Q. Okay. Doctor, moving on to 21 inflammation and ovarian cancer. 22 Generally, on inflammation, can you cite to 23 a published experiment that was conducted in 24 animals in vivo that establishes a role of any 25 particular inflammatory cell or cytokine or</p>
<p style="text-align: right;">Page 287</p> <p>1 certainly I'm citing him several times there. 2 Q. Okay. That's fine. We'll just move 3 on. 4 And, Doctor, just to be clear, I understand 5 your testimony is that it is common knowledge to 6 pathologists that oxidative stress and 7 inflammation are related; correct? 8 A. Yes. 9 Q. Okay. But you are -- we're talking 10 about oxidative stress and redox biology 11 specifically as a field of study or research. 12 You're not an expert in that field of study 13 or research, are you? 14 A. I certainly have read literature in 15 that area. 16 Q. Does that make you an expert? 17 A. I'm -- I mean, I'm familiar with 18 literature in the area. That's -- that's my 19 answer. 20 Q. Okay. But you don't conduct studies in 21 oxidative stress and redox biology, do you? 22 A. I do not conduct studies in oxidative 23 stress and redox biology. 24 Q. You're not currently participating in a 25 study looking at oxidative stress or redox</p>	<p style="text-align: right;">Page 289</p> <p>1 enzyme in tumor regeneration? 2 A. Oh. Let me -- let me bring up my 3 inflammation section. Sorry. I'm just 4 refreshing myself as to what I stated in my 5 report. 6 Oh, this is low battery again. I don't 7 think this is plugged in. 8 MR. ROTMAN: Can we take five minutes 9 off the record? 10 MS. AHERN: Yes. 11 THE VIDEOGRAPHER: Off the record, 12 5:02 p.m. 13 (A recess was taken.) 14 THE VIDEOGRAPHER: Here begins Media 15 No. 6 in today's deposition of Sarah Kane, M.D. 16 Back on the record, 5:28 p.m. 17 (Article entitled "Talcum 18 powder, chronic pelvic inflammation and 19 NSAIDs in relation to risk of epithelial 20 ovarian cancer" marked Exhibit 24.) 21 BY MS. AHERN: 22 Q. Dr. Kane, I'm marking what's been -- 23 well, I'm marking Exhibit 24 to your deposition, 24 which is a copy of the Merritt 2008 publication. 25 And I'm sorry, I don't have an extra. I'm going</p>

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<p>1 to share.</p> <p>2 It's "Talcum powder, chronic pelvic</p> <p>3 inflammatory -- sorry, chronic pelvic</p> <p>4 inflammation and NSAIDs in relation to risk of</p> <p>5 epithelial ovarian cancer."</p> <p>6 And you cite Dr. Merritt's paper a couple of</p> <p>7 times in your report; is that correct?</p> <p>8 A. I believe I cited it, yes.</p> <p>9 Q. I think you cite it as a statistically</p> <p>10 significant positive talc study on Page 17 of</p> <p>11 your report?</p> <p>12 A. Oh, let me get to that, if that's the</p> <p>13 section I'm thinking of.</p> <p>14 Q. There are a couple of places?</p> <p>15 A. There was -- yes. This happened in</p> <p>16 editing. I believe if this is -- so the sentence</p> <p>17 ended up, it originally didn't have the</p> <p>18 "statistically significant." It was just, you</p> <p>19 know, an odds ratio greater than one and listed.</p> <p>20 And then I mistakenly didn't delete. When I</p> <p>21 changed it to "statistically significant," for</p> <p>22 some reason -- I don't know if it happened in the</p> <p>23 editing between additions or something -- somehow</p> <p>24 I seem to remember deleting them. But in the</p> <p>25 final, they ended up all there. So that was a --</p>	<p>1 of multiple publications.</p> <p>2 A. Right.</p> <p>3 Q. You're saying that some of those</p> <p>4 publications shouldn't be in there because you</p> <p>5 added "statistically significant" as a criteria</p> <p>6 later?</p> <p>7 A. Exactly.</p> <p>8 Q. Okay. That's actually not my question</p> <p>9 about Merritt, but thank you.</p> <p>10 A. I knew that was going to come up --</p> <p>11 Q. That's okay.</p> <p>12 A. -- at some point.</p> <p>13 Q. While we're there, since we're sitting</p> <p>14 here looking at this, so these are -- you listed</p> <p>15 out case-control studies addressing talc, and</p> <p>16 they're supposed to be those that have</p> <p>17 statistically significant odds ratios; correct?</p> <p>18 A. That's correct. That was the</p> <p>19 intention.</p> <p>20 Q. And Gertig 2000 is there, and Houghton</p> <p>21 2014 are there, and they're obviously cohort</p> <p>22 studies?</p> <p>23 A. So, again, I think that somehow that</p> <p>24 paragraph got all -- and I didn't catch it in the</p> <p>25 final edits.</p>
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<p>1 MR. ROTMAN: What page was this?</p> <p>2 A. -- typographical error.</p> <p>3 It's in there twice. I noticed it after I</p> <p>4 submitted it, and it was one of those --</p> <p>5 Q. Are you saying Merritt is not</p> <p>6 statistically significant?</p> <p>7 A. So I know which -- again, I'd have -- I</p> <p>8 have to go through. It's been a long day, and</p> <p>9 the names are starting to get all confused.</p> <p>10 Q. Yeah.</p> <p>11 A. But I know that that sentence, with</p> <p>12 "all of those" at the end of that sentence, is</p> <p>13 incorrect because I had changed -- I had meant to</p> <p>14 list cumulatively the statistically significant</p> <p>15 ones and ended up --</p> <p>16 Q. Okay. So just to clarify for the</p> <p>17 record, on Page 17, we're talking about the first</p> <p>18 full paragraph that says, "In addition to the</p> <p>19 Cramer 1982 study, numerous other case-control</p> <p>20 studies addressing talc use and ovarian cancer</p> <p>21 have shown statistically significant odds ratios</p> <p>22 greater than one indicating talc use is</p> <p>23 associated with an increased ovarian cancer</p> <p>24 risk."</p> <p>25 And then there's a string cite with a number</p>	<p>1 Q. Okay.</p> <p>2 A. I know that that was at least a</p> <p>3 different paragraph at first, possibly two</p> <p>4 paragraphs that got condensed. And then somehow,</p> <p>5 the references didn't get changed in the final.</p> <p>6 Q. Okay. Do you happen to know -- and if</p> <p>7 you don't it's okay -- but do you happen to know</p> <p>8 which of these studies should be there and which</p> <p>9 should be removed?</p> <p>10 A. Off -- I would want to look just to</p> <p>11 make sure.</p> <p>12 Q. Okay.</p> <p>13 A. But I'm -- if I am -- I'd want to look</p> <p>14 just to make sure, but I know there are some that</p> <p>15 should not be there.</p> <p>16 Q. All right. But looking at Merritt,</p> <p>17 there are a couple of places where Merritt is</p> <p>18 cited in your report. One is Page 17 in that</p> <p>19 paragraph we just looked at. Another is Page 28</p> <p>20 in Section -- the "Pooled study regarding talc</p> <p>21 use and ovarian cancer" section.</p> <p>22 It says some -- let's see, you're talking</p> <p>23 about the advantages of pooled studies, and you</p> <p>24 cited Merritt 2008.</p> <p>25 A. Okay.</p>

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<p style="text-align: right;">Page 294</p> <p>1 Q. And then on Page 35, Merritt is cited. 2 "Studies evaluating duration and frequency of 3 perineal use, most have found an increased risk 4 of ovarian cancer with increased exposure." 5 We already went through this paragraph 6 earlier -- 7 A. Yeah. Yeah. 8 Q. -- and discussed Merritt a little bit 9 in that context. 10 MR. ROTMAN: Page 30 -- the last one 11 was Page 35? 12 MS. AHERN: Thirty-five. Yeah. I 13 apologize. We may not have discussed Merritt. 14 BY MS. AHERN: 15 Q. But looking at Merritt now, you're 16 aware that Merritt looked specifically at 17 inflammatory conditions as part of their 18 exploration of the hypothesis that chronic 19 inflammation could lead to ovarian cancer; is 20 that right? 21 A. Yes. There was a component from what I 22 remember. 23 Q. They say in the abstract that "Chronic 24 inflammation has been proposed as the possible 25 causal mechanism that explains the observed</p>	<p style="text-align: right;">Page 296</p> <p>1 endometriosis. 2 And do you see if you turn to -- I'm trying 3 to get through this quickly. You're welcome to 4 point out anything you want, but I kind of want 5 to move us along. 6 A. Okay. 7 Q. If you look at the "Discussion" 8 section, I, unless I missed it, on Page 174, the 9 right-hand column, second full paragraph, they 10 note that "It has been hypothesized that talc is 11 linked to ovarian cancer development through 12 inflammation. However, evidence linking an 13 inflammatory response with talc contamination of 14 the ovaries is lacking." 15 Do you agree or disagree with that statement 16 that evidence linking an inflammatory response 17 with talc contamination of the ovaries is 18 lacking? 19 A. I don't know if I would phrase it that 20 way. Have there been studies that have followed 21 talc from application up to the ovaries and 22 documenting an inflammatory response after talc? 23 No. There's not going to be that study. 24 That would be -- I don't think you could do 25 that study today with talc being called by the</p>
<p style="text-align: right;">Page 295</p> <p>1 association between certain risk factors such as 2 the use of talcum powder or talc in the pelvic 3 region and epithelial ovarian cancer." 4 Do you see that? It's in the abstract, the 5 first sentence? 6 A. Yeah. Okay. The first sentence. 7 Q. Okay. They go on to say, "To address 8 the issue, we evaluated the potential role of 9 chronic local ovarian inflammation in the 10 development of the major subtypes of epithelial 11 ovarian cancer." 12 Do you see that? 13 A. Yes. 14 Q. Okay. And just want to ask you: They 15 conducted the study as a case-control study 16 looking at 2319 women with epithelial ovarian 17 cancer; correct? 18 A. I don't remember the exact number, but 19 I will -- I will -- 20 Q. I think that's -- that's okay. 21 A. I don't remember the exact number. 22 Q. Okay. So they looked at a number of 23 factors that are theoretically associated with 24 chronic inflammation, didn't they, including 25 pelvic inflammatory disease and talc use,</p>	<p style="text-align: right;">Page 297</p> <p>1 IARC a possible carcinogen. I don't think you 2 could design that study right now and do that in 3 women. 4 But, again, I think -- I think it's still a 5 highly compelling, plausible mechanism because we 6 know talc can cause inflammation, and 7 inflammation is associated with certain cancers, 8 including certain types of ovarian cancers. 9 So I don't know if I would state it that 10 way. 11 Q. When you say inflammation is associated 12 with ovarian cancer, what studies are you 13 referring to? 14 A. I'm referring to, for example, clear 15 cell carcinomas that have arisen from 16 endometriotic lesions that we've talked about 17 before. 18 Q. And those cells are -- the originating 19 cells are thought to come from the endometrium 20 itself, the uterus; correct? 21 A. I don't know if we know for sure. I 22 mean, is it endometriosis that's in the ovary 23 causing chronic inflammation in the ovarian cells 24 that are causing the clear cell? I don't know if 25 that's been completely delineated.</p>

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<p style="text-align: right;">Page 298</p> <p>1 Q. But there are markers that will 2 distinguish ovarian surface epithelial cells from 3 endometrioid cells which resemble endometrial 4 cells; correct? 5 A. There are some stains that you can do. 6 But, again, I don't know if it's going to be -- 7 been completely elucidated. 8 Q. Are you aware of recent studies that 9 have demonstrated that there is some abnormality 10 in the endometrium of women who develop 11 endometriosis when compared to women who don't 12 develop endometriosis? 13 A. I'm aware that retrograde migration of 14 the endometrium is thought to -- has been 15 associated with endometriosis. I don't know what 16 you mean by "abnormalities" of the -- you have to 17 be more specific. I can't -- 18 Q. I don't have the publication with me. 19 I was just asking if you were aware of those 20 studies. 21 A. I probably read them at some point, but 22 off the top of my head, I'm not really sure 23 without knowing more specifically. 24 Q. And would you agree that the studies, 25 though, that show a decreased risk of ovarian</p>	<p style="text-align: right;">Page 300</p> <p>1 inflammatory mechanism in the development of 2 epithelial ovarian cancer. However, experimental 3 evidence that perineal talc use elicits an 4 inflammatory response in the ovaries is lacking, 5 and overall, we conclude that chronic 6 inflammation does not play a major role in 7 development of ovarian cancer." 8 Is there a reason you didn't cite the 9 Merritt study in your report specifically when 10 discussing evidence of chronic inflammation and 11 ovarian cancer, a link between those two? 12 A. In the places that I -- let me just 13 double-check. Places that I mention, was I 14 not -- I wasn't talking about inflammation. Is 15 that what you're -- 16 Q. Yes. You agree you cited Merritt in 17 several places in your report? 18 A. Yes. 19 Q. But you didn't cite anything about the 20 inflammation findings from Merritt. 21 A. I'm not sure I can completely agree 22 with their conclusion. It's true we don't 23 have -- like I mentioned before, we don't have a 24 study that has looked at women who use talc, 25 follow it up, and then see chronic inflammation</p>
<p style="text-align: right;">Page 299</p> <p>1 cancer for women who have tubal ligation are 2 studies -- well, are more highly associated with 3 endometrioid clear cell carcinomas than with 4 high-grade serous? 5 A. With tubal ligation, off the top of my 6 head, I believe that's -- that that's the case. 7 But with salpingectomy, which removes the 8 fallopian tube fimbriae, there's -- that 9 decreases the risk of serous carcinomas. 10 Q. To a lesser extent, then, the decrease 11 for clear cell and endometrioid, which some 12 people have suggested supports the retrograde 13 migration of endometrial cells into the abdominal 14 cavity? 15 A. Some people have said that that 16 supports the retrograde migration of the 17 endometrial cells. That is correct. 18 Q. And I got off topic. We're looking at 19 Merritt. Page 174, if you look, let's see -- 20 here it is. Sorry. I apologize, on Page 175. 21 The very bottom of the summary paragraph, it 22 says, "The elevation in ovarian cancer risk 23 associated with use of talc in the perineal 24 region that we and others have observed has been 25 regarded as the main evidence supporting an</p>	<p style="text-align: right;">Page 301</p> <p>1 in the ovary. 2 But I think that's going to be -- again, we 3 don't know how long that chronic inflammation is 4 going to be there. We don't know what dose is 5 getting into the ovary. 6 I still think -- and, again, this is the 7 plausibility part of it -- I think there's still 8 compelling evidence that talc can cause an 9 inflammatory response that would explain the risk 10 of increased risk of ovarian cancer with talcum 11 powder products. 12 So, I mean, I certainly read this. It had 13 some good information in it. I don't think I was 14 purposely trying to leave out something that had 15 evidence. This was their opinion. 16 And I'm -- I don't know if I would phrase it 17 that way, the exact words that they use. 18 Q. Well, if those are exactly their 19 findings here -- if you look at the top of the 20 summary paragraph, "In summary, most factors that 21 could potentially cause ovarian inflammation such 22 as pelvic inflammatory disease, HPV infection, 23 and postpubertal mumps were not associated with a 24 significant elevation in ovarian cancer risk in 25 our study. In addition, the expected corollary,</p>

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<p>1 an inverse association with regular use of 2 anti-inflammatory medications, was also not 3 observed -- or was not observed." 4 A. Yes. Yeah. Yeah. 5 Q. They looked at multiple sources or 6 multiple causes of inflammation in the pelvic 7 region and did not find an association with the 8 risk of ovarian cancer, and they didn't find a 9 decreased risk in people that used 10 inflammatory -- anti-inflammatory medications. 11 A. I think I mentioned -- 12 Q. So this is an inflammation study, isn't 13 it? 14 A. Yeah. I think I mentioned in -- about 15 NSAIDs that I might have cited them in that 16 section, that the evidence was not consistent 17 with NSAIDs, if I remember correctly. 18 I definitely looked at this paper when I was 19 looking at NSAID and aspirin use and certainly 20 inflammation as well. So... 21 Q. It's actually not cited anywhere with 22 NSAID use or regarding inflammation at all. 23 So maybe it was an earlier draft and was 24 removed at some point? 25 A. It's possible.</p>	<p>1 Q. I'm sorry. I'm just referring 2 generally. 3 Do your opinions, in part, depend on the 4 finding of talc in ovaries? 5 A. No. Because I think, again, it's 6 difficult to find talc in the ovaries. So I 7 would not expect to see -- to find, to 8 histologically find talc in every ovary of a 9 woman who has used talcum powder products. I 10 think that would be extremely difficult to do in 11 every patient. 12 And I know we talked about the MUC-1 theory 13 earlier, but if that is the mechanism, that would 14 not require talc to get to the ovary. 15 So, no, I don't think it's necessary to find 16 talc in the ovary in every woman to come -- 17 that's a user. 18 Q. Let's talk about evidence for 19 talc-induced inflammation in the ovary. 20 For instance, you've cited the Heller study 21 from 1996 in your "Migration translocation, 22 inhalation, and lymphatic transport" section on 23 Page 14. 24 A. Mm-hmm. 25 Q. Heller actually states in their study</p>
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<p>1 Q. And you also -- you cite -- you do cite 2 some of the NSAID studies and aspirin studies, 3 but you leave out others. You leave out Baandrup 4 2013, which was a negative study; Bonovas, 2005, 5 which was a negative study; Ni, 2012, which was a 6 negative study. 7 When you did your review of inflammation 8 including anti-inflammatory medications and the 9 risk of ovarian cancer, did you pull out more 10 studies in review than you actually included in 11 your report? 12 A. Yes. There are definitely more studies 13 than were cited in my report. 14 Q. Is there a reason you didn't cite the 15 negative studies? 16 A. I didn't intentionally leave out the 17 negative studies, but I do mention that the 18 evidence had been inconsistent with NSAID. 19 Q. Okay. And you mentioned the Heller 20 study in a couple of places. You mentioned 21 several times that part of your plausibility 22 opinions involve the fact that talc has been 23 observed in the ovaries; correct? 24 A. Can you show me? I'm sorry. I just 25 want to make sure.</p>	<p>1 that they did not find on their H&amp;E slides any 2 response -- any expected response to talc 3 particles. 4 Do you remember that? 5 A. I do remember that vaguely. Yes. 6 Q. Did any of the studies that you cite in 7 that section for the proposition that talc has 8 been found in ovarian tissue, did any of those 9 find a reaction to talc in the ovaries? 10 A. I don't believe the studies that have 11 found talc in the ovaries have all looked for 12 chronic inflammation. Some of them, if I'm 13 remembering correctly, I don't know if they all 14 looked histologically; but the ones that did, I 15 don't believe they had mentioned finding chronic 16 inflammation near the talc particles. 17 But again, you know, depending on how long 18 that inflammatory response is going to be there, 19 depending how long that particular talc particle 20 has been there, you wouldn't necessarily expect 21 to still see it 20 years later. 22 Q. Okay. In the Heller study, they looked 23 at ovarian tissue -- ovaries from one of their 24 subjects who had 1.7 or approximately 25 1.669 million particles per gram of wet weight by</p>

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<p>1 electron microscopy and found on hematoxylin and</p> <p>2 eosin stain slides from the analyzed sections of</p> <p>3 the tissue that no evidence of response to talc</p> <p>4 such as foreign body giant cell reactions or</p> <p>5 fibrosis in the tissue.</p> <p>6 Is that consistent with the other studies</p> <p>7 that have reported findings from H&amp;E have also</p> <p>8 reported no response to talc or supposed talc</p> <p>9 they found?</p> <p>10 What is an alternative explanation for how</p> <p>11 microscopists doing these sorts of studies might</p> <p>12 find talc by TEM or SEM without any histologic</p> <p>13 response --</p> <p>14 MR. ROTMAN: Objection.</p> <p>15 Q. -- to talc in the tissue?</p> <p>16 A. Well, I think I addressed that a little</p> <p>17 earlier. Again, I don't know -- we don't know</p> <p>18 how long a chronic inflammatory response would be</p> <p>19 there after a particular talc particle lands on</p> <p>20 the ovary.</p> <p>21 But the important thing would be that that</p> <p>22 chronic inflammation, the initial chronic</p> <p>23 inflammation, whenever that may be, however long</p> <p>24 it is there, causes oxidative stress that induces</p> <p>25 an oncogenic change in an ovarian cell or</p>	<p>1 MS. AHERN: What number are we on?</p> <p>2 COURT REPORTER: Twenty-five.</p> <p>3 MS. AHERN: Twenty-five.</p> <p>4 MR. TISI: So 24 was --</p> <p>5 MS. AHERN: We'll wait.</p> <p>6 (Article entitled "The</p> <p>7 relationship between perineal cosmetic talc</p> <p>8 usage and ovarian talc particle burden"</p> <p>9 marked Exhibit 25.)</p> <p>10 A. I believe they went through standard</p> <p>11 electron microscopy methods, which controls for</p> <p>12 contamination.</p> <p>13 BY MS. AHERN:</p> <p>14 Q. How?</p> <p>15 A. I don't know if it goes through the</p> <p>16 whole -- but they're very careful in how they</p> <p>17 handle tissue before they prep for electron</p> <p>18 microscopy.</p> <p>19 Q. Doctor, do you know where they got the</p> <p>20 tissue from?</p> <p>21 A. Yeah. It's listed.</p> <p>22 Q. Did they collect the tissue themselves</p> <p>23 from the patient in a particulate-free</p> <p>24 environment and handle it with particulate-free</p> <p>25 gloves in containers, or did they get it from</p>
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<p>1 fallopian tube cell, for that matter.</p> <p>2 So -- and these are very small studies that</p> <p>3 looked at histologic -- that looked</p> <p>4 histologically for talc in these ovaries.</p> <p>5 So, you know, I don't necessarily think -- I</p> <p>6 don't think that you would have to find chronic</p> <p>7 inflammation if you're looking at an ovary at a</p> <p>8 particular point in time when we're talking about</p> <p>9 long-term talc use from, you know, up to 20 years</p> <p>10 ago or something.</p> <p>11 Q. Well, if they're finding 1.7 million</p> <p>12 particles per gram of wet tissue right then and</p> <p>13 there, and their slides from that time period</p> <p>14 don't show any response whatsoever to talc that</p> <p>15 they would expect to see, what's an alternative</p> <p>16 explanation?</p> <p>17 A. An alternative explanation is that</p> <p>18 there was chronic inflammation, and it has since</p> <p>19 resolved.</p> <p>20 Q. How about there might be contamination</p> <p>21 of their samples with talc, which is ubiquitous</p> <p>22 in many laboratories?</p> <p>23 A. I believe they -- I have to look at the</p> <p>24 study to -- do you have the study?</p> <p>25 MR. ROTMAN: Thank you. What number?</p>	<p>1 hospital paraffin-embedded tissue?</p> <p>2 If you look on Page 1508, "Ovarian tissue in</p> <p>3 blocks was reparafrinized, rehydrated, blotted dry</p> <p>4 and weighed, and then digested with reagents."</p> <p>5 A. So I think these women were talc users.</p> <p>6 I'm trying to find controls that they had ovaries</p> <p>7 from -- if I remember correctly, they had ovaries</p> <p>8 from fetal cases that did not show talc, if I</p> <p>9 remember correctly. I'm trying to find that.</p> <p>10 Yeah. "In addition, the ovaries of two</p> <p>11 stillborn fetuses were analyzed as negative</p> <p>12 controls."</p> <p>13 Q. Does it say anything about where those</p> <p>14 stillborn fetus ovaries came from and if they</p> <p>15 were handled in the same hospital in the same way</p> <p>16 that the paraffinized blocks were handled?</p> <p>17 A. If they didn't have a separate section</p> <p>18 of their methods how they handled it, it would be</p> <p>19 the same methodology.</p> <p>20 Q. Well, assuming it's not contamination</p> <p>21 and there's still no reaction to talc, another</p> <p>22 alternative explanation might be that talc</p> <p>23 doesn't cause chronic inflammation in the</p> <p>24 ovaries.</p> <p>25 A. But they didn't find talc in their</p>

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<p style="text-align: right;">Page 310</p> <p>1 negative controls, which were fetal females that 2 would never have been exposed to talc. 3 Q. Except for after the tissues were taken 4 from the fetuses and processed? 5 A. I'm just trying to find where they -- 6 what they did. 7 Q. What I wonder and what I don't think is 8 in the paper, unless you can find it, is an 9 explanation for how the fetal ovaries were 10 obtained and processed. 11 Did they come from the same hospital 12 system -- 13 A. It would be the same. 14 Q. -- from the laboratory so that any 15 contamination that occurred to those tissues 16 prior to the Heller group getting them was 17 accounted for? 18 Or did they purchase them separately through 19 a company or something else that handled them 20 differently from the hospital samples? 21 MR. ROTMAN: Objection. 22 A. If those were obtained differently, it 23 should have been in the methodology. So the fact 24 that it's not there, the next sentence after they 25 say, "In addition, the ovaries of two stillborn</p>	<p style="text-align: right;">Page 312</p> <p>1 something that would happen over days. Chronic 2 inflammation is generally longer, but it still 3 resolves. 4 Q. And are -- for instance, pelvic 5 inflammatory disease is -- the effects of pelvic 6 inflammatory disease can be seen by pathologists 7 for a very long time; correct? 8 A. You can see fibrosis. So... 9 Q. And one of the things that you 10 mentioned earlier is that talc can cause 11 fibrosis? 12 A. Talc can cause fibrosis. You get -- in 13 the ovary, however, you will get surface 14 fibrosis, generally, from the mesothelial cells 15 in the surface. 16 But, again, you're not always going to have 17 fibrosis with chronic inflammation, either. 18 Q. If it's chronic inflammation that is 19 significant enough to lead to a transformative 20 event, shouldn't you expect to see some evidence 21 of that chronic inflammation? 22 A. Well, we don't know how much chronic 23 inflammation is necessary to cause a carcinogenic 24 effect. 25 Q. By analogy, wouldn't you look at</p>
<p style="text-align: right;">Page 311</p> <p>1 fetuses were analyzed as negative controls," that 2 is where, if it had been a different methodology 3 or different purchased ovarian cell blocks from 4 fetuses, which I have never -- anyway, it would 5 be -- it would be there. And it's not. 6 Q. Hmm. So my next question is: I had 7 asked you earlier if there was an alternative 8 explanation for why there's no tissue response 9 seen in this study to talc particles, and you 10 said it could be because the chronic inflammation 11 was there and not there at the time that they 12 looked at the H&amp;Es? 13 A. Yeah. I mean, you're looking at an 14 ovary at a very -- at one time point. So we 15 don't know how long those talc particles were 16 there. We don't know if -- how long -- we don't 17 know how long the chronic inflammation is there. 18 But the important thing is that the chronic 19 inflammation would cause an event to change to an 20 oncogenic phenotype, gene type. 21 Q. So chronic inflammation is, by 22 definition, chronic; correct? Doesn't just -- it 23 doesn't just resolve in a couple of days. 24 It's ongoing; is that correct? 25 A. It is -- acute inflammation would be</p>	<p style="text-align: right;">Page 313</p> <p>1 something like ulcerative colitis and colon 2 cancer since that seems to be a fairly 3 well-established association? 4 A. Yes. And as soon as patients are 5 diagnosed with ulcerative colitis and Crohn's 6 disease, they are carefully followed at the 7 beginning. We don't wait 20 years to start 8 following them. We know that, you know, the risk 9 is there. As soon as they're diagnosed, we know 10 there is a risk for increased cancer, so we start 11 surveying them. 12 Q. But there's massive evidence of 13 inflammation -- tissue-damaging inflammation in 14 ulcerative colitis; correct? 15 A. Not always massive, but there's chronic 16 inflammation. 17 Q. Throughout the entire GI tract or 18 bowel? 19 A. In -- it's not always the whole, but 20 yeah, there's chronic inflammation in the 21 intestines. 22 Q. There's nothing in the literature that 23 suggests that talc causes that kind of an 24 inflammatory reaction, is there? 25 A. That talc causes a chronic</p>

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<p style="text-align: right;">Page 314</p> <p>1 inflammation?</p> <p>2 Q. That talc causes that sort of chronic</p> <p>3 inflammatory reaction.</p> <p>4 A. Well, I showed you some excerpts where</p> <p>5 they mention lymphocytic and plasmacytic</p> <p>6 inflammation due to talc. We know that talc</p> <p>7 causes an acute inflammation. I know we weren't</p> <p>8 talking about acute inflammation, but we know it</p> <p>9 causes acute inflammation in the -- after a</p> <p>10 pleurodesis. And I'm sure you could have</p> <p>11 lymphocytes in plasma cells there too.</p> <p>12 Again, I don't think it's the -- sure. The</p> <p>13 amount and duration of chronic inflammation, I</p> <p>14 mean, would that increase the risk? But even a</p> <p>15 small amount of chronic inflammation for a</p> <p>16 relatively short period of time, I think it's</p> <p>17 plausible.</p> <p>18 And, again, this is all under the plausible</p> <p>19 thing that this would cause a mutagenic effect.</p> <p>20 Q. Can you name other chronic inflammatory</p> <p>21 conditions that are not associated with cancer?</p> <p>22 A. Chronic inflammatory conditions that</p> <p>23 are not associated with cancer? Well, I'm not</p> <p>24 sure we absolutely know every -- that a chronic</p> <p>25 inflammatory condition won't cause a cancer,</p>	<p style="text-align: right;">Page 316</p> <p>1 Q. Have you ever diagnosed a patient with</p> <p>2 a talc-related ovarian cancer?</p> <p>3 A. It's entirely possible that I have, but</p> <p>4 I have not used polarized light microscopy on</p> <p>5 ovarian tumors, so it's possible I have and</p> <p>6 didn't look for talc -- didn't look for talc.</p> <p>7 MR. KLATT: Objection. Nonresponsive.</p> <p>8 Q. My question was: Have you ever</p> <p>9 diagnosed a patient with a talc-related ovarian</p> <p>10 cancer, meaning you have said, "Your cancer is</p> <p>11 related to talc use"?</p> <p>12 A. Well, first of all, I wouldn't have</p> <p>13 said that if I'm not looking for talc.</p> <p>14 But secondly, in our pathology reports, even</p> <p>15 though we're thinking and looking at causation,</p> <p>16 we're not necessarily putting in our individual</p> <p>17 patient reports what caused their cancer.</p> <p>18 We're certainly putting the diagnosis</p> <p>19 together with their medical history and their --</p> <p>20 to kind of make all the pieces fit together, but</p> <p>21 we're not necessarily in every patient putting</p> <p>22 out a report on what causes their cancer.</p> <p>23 MR. KLATT: Objection. Nonresponsive.</p> <p>24 MS. AHERN: Objection. Nonresponsive.</p> <p>25 Q. I just want to know if you've ever</p>
<p style="text-align: right;">Page 315</p> <p>1 but -- so I'm not really sure. I'm not really</p> <p>2 sure what you're getting at.</p> <p>3 Q. Can you list five chronic inflammatory</p> <p>4 conditions?</p> <p>5 A. That don't cause --</p> <p>6 Q. Just list five chronic inflammatory</p> <p>7 conditions.</p> <p>8 A. Well, we have rheumatoid arthritis that</p> <p>9 increases risk of lymphomas. We have</p> <p>10 Helicobacter pylori infections that increase</p> <p>11 gastric cancer. We have the ulcerative colitis,</p> <p>12 Crohn's disease, that increase the risk of</p> <p>13 cancer. Agent exposures like asbestos that</p> <p>14 causes chronic inflammation and causes cancer.</p> <p>15 HPV infection causes cancer. I mean...</p> <p>16 Q. Can you name one that doesn't involve a</p> <p>17 virus or an underlying immune dysfunction?</p> <p>18 A. I named asbestos.</p> <p>19 Q. Asbestos.</p> <p>20 And was there another?</p> <p>21 A. Again, I don't know if we have all the</p> <p>22 data on potential carcinogens and whether or not</p> <p>23 they cause chronic inflammation for sure. I</p> <p>24 think that, you know, we're still getting that</p> <p>25 data.</p>	<p style="text-align: right;">Page 317</p> <p>1 actually diagnosed a patient with a talc-related</p> <p>2 ovarian cancer. It sounds like the answer is no.</p> <p>3 If it is, it's okay. I need an answer.</p> <p>4 A. I'm trying to answer your question.</p> <p>5 Honestly, it's entirely possible that I have.</p> <p>6 But have I specifically put in a patient's</p> <p>7 report, "This ovarian cancer was caused by talc,"</p> <p>8 no.</p> <p>9 Q. Thank you. That's all I was asking.</p> <p>10 What about at tumor boards? Do you attend</p> <p>11 tumor boards?</p> <p>12 A. I do.</p> <p>13 Q. Have you ever suggested in a tumor</p> <p>14 board meeting with other colleagues that a</p> <p>15 particular patient's ovarian cancer was caused by</p> <p>16 talc use?</p> <p>17 A. I've certainly discussed with</p> <p>18 oncologists and radiation oncologists about my</p> <p>19 recent work. Again, it's been only in the last</p> <p>20 year and a half that I have really done this deep</p> <p>21 dive in this literature.</p> <p>22 And I've certainly talked to radiation</p> <p>23 oncologists, oncologists about it at tumor boards</p> <p>24 in a way of sort of educating them about my</p> <p>25 findings, but we haven't discussed in the context</p>

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<p style="text-align: right;">Page 318</p> <p>1 of a particular patient. 2 Q. And were these discussions with 3 radiation oncologists, were these people that 4 focused on -- if they focus on -- gynecologic 5 malignancies? Were they more pulmonary? Is 6 there a difference with radiologists in terms of 7 specialty? 8 A. There are some subspecialties. In this 9 one, they were more general radiation 10 oncologists. 11 Q. Okay. 12 MS. AHERN: How much time do we have? 13 THE VIDEOGRAPHER: Fifteen minutes. 14 MS. AHERN: I'm going to turn it over 15 to my colleagues so they have an opportunity to 16 ask questions. Thank you very much. I 17 appreciate it. 18 THE WITNESS: Thank you. 19 MR. KLATT: How much time do we have? 20 We're at 6:37 right now. 21 Are you ready for me to continue? 22 CROSS-EXAMINATION 23 BY MR. KLATT: 24 Q. Dr. Kane, are you ready to continue? 25 A. Yes.</p>	<p style="text-align: right;">Page 320</p> <p>1 asbestos in it. 2 Are you choosing to believe the plaintiffs' 3 asbestos experts over Ms. Pier's testimony? 4 MR. TISI: Objection. 5 A. Again, I think these were pieces of 6 information for me. I wasn't relying on her -- 7 the exhibit from her testimony for my general 8 causation. I wasn't -- and I didn't see 9 Dr. Longo's reports until very late in my process 10 from what I recall. 11 It's interesting information for me. It's 12 informative in that if the talcum powder products 13 cause [sic] asbestos, that certainly lends 14 significance to plausibility. But I'm -- 15 MR. ROTMAN: Do you want to reread your 16 answer there? I think you misspoke. 17 THE WITNESS: Okay. Sorry. 18 A. Yes. I did. If the talcum powder 19 contains asbestos, that certainly adds to the 20 plausibility. But I'm not opining on whether or 21 not talcum powder products contain asbestos. 22 Q. And you wouldn't have the expertise to 23 decide that Dr. Longo's testimony about asbestos 24 in talc is more credible than Ms. Pier's 25 testimony about asbestos in talc, do you?</p>
<p style="text-align: right;">Page 319</p> <p>1 Q. Can you hear me okay? 2 A. Yes. 3 Q. Yes. Dr. Kane, my name is Mike Klatt, 4 and I represent a company called Imerys Talc 5 America in this case. 6 Before this lawsuit, have you ever heard of 7 Imerys Talc America? 8 A. I don't believe I had, no. 9 Q. Do you know what Imerys Talc America 10 does? 11 A. From my understanding, they mine talc, 12 and they supply -- they're the talc -- one of the 13 talc suppliers for Johnson &amp; Johnson. 14 Q. You said earlier you reviewed an 15 exhibit of Julie Pier's deposition. 16 Do you know who Julie Pier is? 17 A. I know she was a designated 18 representative. I don't know if it was for J&amp;J 19 or for Imerys off the top of my head. 20 Q. Ms. Pier works at Imerys, and she's an 21 expert microscopist and at analyzing talc for any 22 extraneous substances like asbestos. 23 She testified that the evidence you looked 24 at did not indicate in any way that talc that 25 ended up in Johnson &amp; Johnson's baby powder had</p>	<p style="text-align: right;">Page 321</p> <p>1 A. I have a, I would say, cursory 2 knowledge of how they would test for asbestos. I 3 couldn't say that I am an expert in the methods 4 that they use to detect asbestos. 5 Q. But my specific question is: You don't 6 have the expertise to determine that Dr. Longo's 7 testimony about asbestos and talc is more 8 credible with or more believable or more 9 scientifically valid or less scientifically valid 10 than Ms. Pier's testimony about asbestos and 11 talc; correct? 12 That's my question. 13 A. Again, it's pieces of information for 14 me. I don't know anything, really, about 15 Dr. Longo versus Ms. Pier. I just have seen the 16 exhibit from Ms. Pier's testimony and Dr. Longo's 17 report, but I don't have more information nor 18 have I really sought it out about their 19 credentials. I was just using it as pieces of 20 information. 21 Q. But again my question is: You have no 22 ability or expertise on your own to judge whether 23 Ms. Pier's testimony that there's not asbestos in 24 talc is correct or Dr. Longo's testimony is 25 correct. That's not an area of your expertise;</p>

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<p>1 correct?</p> <p>2 A. It -- I wouldn't say I'm an expert in</p> <p>3 that area.</p> <p>4 Q. You mentioned earlier in response to</p> <p>5 Ms. Ahern's questions, you talked about heavy</p> <p>6 metals.</p> <p>7 Are you aware that IARC has not singled out</p> <p>8 a single heavy metal as a cause of ovarian</p> <p>9 cancer?</p> <p>10 A. Yes. I have seen that. I have</p> <p>11 reviewed the IARC monograph on heavy metals, and</p> <p>12 I'm aware.</p> <p>13 But, again, it's another sort of piece of</p> <p>14 the plausibility puzzle. If we -- we know that</p> <p>15 some of them are either listed as carcinogens or</p> <p>16 probable carcinogens. If they're in the talcum</p> <p>17 powder product, that's just another piece of the</p> <p>18 biological plausibility puzzle. And I --</p> <p>19 Q. Well, is it your -- I'm sorry. I</p> <p>20 didn't mean to cut you off.</p> <p>21 A. No. Sorry.</p> <p>22 Q. Is it your testimony that if something</p> <p>23 is considered a carcinogen for one organ system</p> <p>24 by IARC, that it's capable of causing cancer in</p> <p>25 all organ systems?</p>	<p>1 at the end of the answer before you started your</p> <p>2 next question.</p> <p>3 A. So I'm aware that they're in these</p> <p>4 things. What I'm looking at is a product that's</p> <p>5 used frequently and for -- in a lot of women for</p> <p>6 a long duration of time. So their exposure -- if</p> <p>7 they are in the talcum powder, their exposure to</p> <p>8 those heavy metals would be greater than the</p> <p>9 exposure they're getting in the environment.</p> <p>10 Q. Those same, exact heavy metals are in</p> <p>11 drinking water, bottled water, food, and</p> <p>12 multivitamins that people take every single day,</p> <p>13 and there's no evidence that they cause ovarian</p> <p>14 cancer; correct?</p> <p>15 A. There has not been a link with heavy</p> <p>16 metals to ovarian cancer specifically as of yet.</p> <p>17 Q. And there's no evidence you're aware of</p> <p>18 that the tissue levels of any heavy metals are</p> <p>19 higher in talc users than in women who never used</p> <p>20 talc; correct?</p> <p>21 A. I don't -- I'm not aware of that study</p> <p>22 being done.</p> <p>23 Are you talking tissue levels?</p> <p>24 Q. Blood levels --</p> <p>25 A. Blood levels.</p>
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<p>1 A. As I've testified several times here</p> <p>2 today, I think different tissues respond in</p> <p>3 different ways to different carcinogens. So I</p> <p>4 would not make a blanket statement that a</p> <p>5 carcinogen in one site will definitely cause</p> <p>6 cancer in another site.</p> <p>7 However, having carcinogens, known</p> <p>8 carcinogens in a product, it can add to the</p> <p>9 biological plausibility. And we're not talking</p> <p>10 about these heavy metals sort of in the</p> <p>11 environment. I mean, these are -- there's</p> <p>12 evidence that they are in a product that's used</p> <p>13 regularly and frequently.</p> <p>14 Q. Are you -- are you aware that the same,</p> <p>15 exact heavy metals are in bottled drinking water?</p> <p>16 A. So, again, I don't know what the levels</p> <p>17 of these heavy metals are in drinking water. I</p> <p>18 know that they are found in the environment</p> <p>19 commonly.</p> <p>20 Q. Are you aware they're in foods?</p> <p>21 A. I'm aware that they are in the</p> <p>22 environment and foods regularly. Yes. But --</p> <p>23 Q. Are you aware they're in multivitamins?</p> <p>24 MR. ROTMAN: Wait. Wait.</p> <p>25 I was hearing a "but" and not a period</p>	<p>1 Q. -- tissue levels. Anything you want.</p> <p>2 You're -- there's no medical or scientific</p> <p>3 evidence that you would tell this court that the</p> <p>4 levels of heavy metals in women who use talcum</p> <p>5 powder in the genital area are higher than women</p> <p>6 who have never used talcum powder?</p> <p>7 A. I'm not aware of studies that have been</p> <p>8 done that have looked at the levels of those</p> <p>9 heavy metals in ovarian tissue or blood levels.</p> <p>10 Q. Earlier you mentioned there was a study</p> <p>11 about changing gene expression in the presence of</p> <p>12 talc in mesothelial cells?</p> <p>13 A. Yes.</p> <p>14 Q. The mere fact that you have changing</p> <p>15 gene expression in no way implies something is</p> <p>16 carcinogenic; correct?</p> <p>17 A. It -- it's evidence that it's changing</p> <p>18 gene expression within those cells, and --</p> <p>19 Q. If -- I'm sorry. Go ahead.</p> <p>20 A. And the genes in that study that had</p> <p>21 increased expression are involved in the</p> <p>22 inflammatory -- are pieces in the inflammatory</p> <p>23 response.</p> <p>24 Q. You're aware that many of those genes</p> <p>25 in that study were antioxidant genes and</p>

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<p style="text-align: right;">Page 326</p> <p>1 anti-inflammatory genes that were elevated; 2 correct? 3 A. They can regulate or deregulate, and I 4 think it's interesting -- let's say that they 5 were antioxidant -- they were producing 6 antioxidant enzymes. I think that is evidence 7 that it's trying -- that the cell is trying to 8 respond and is trying to prepare itself for an 9 insult, an inflammatory insult. Otherwise, why 10 would that gene be expressed? 11 So, I mean, there's increased and decreased 12 regulation. 13 Q. But, Dr. Kane, you're aware that 14 strenuous exercise can increase gene expression 15 of prooxidants, antioxidants, proinflammatory, 16 anti-inflammatory proteins; correct? 17 A. Strenuous exercise can increase 18 antioxidants in proinflammatory, 19 anti-inflammatory proteins. 20 But, again, I'm opining about a product that 21 someone is going to be using regularly with 22 frequency over a long period of time. 23 Q. You're aware that -- 24 A. It just adds to the -- I'm not -- you 25 know, I don't have an opinion about whether or</p>	<p style="text-align: right;">Page 328</p> <p>1 MR. KLATT: Can we mark that? 2 MR. ROTMAN: Can we get a time check? 3 THE VIDEOGRAPHER: 6:30. 4 MR. ROTMAN: Thank you. 5 (Article entitled "Pycnogenol 6 reduces Talc-induced Neoplastic 7 Transformation in Human Ovarian Cell 8 Cultures" marked Exhibit 26.) 9 MS. AHERN: That's 26. 10 Q. Referring to Exhibit 26, Dr. Kane, is 11 this the Buz'Zard study you were mentioning 12 earlier? 13 A. Yes, this is it. 14 Q. And if you'll flip over to Page 3 -- 15 excuse me, 582, Figure 3, do you see Figure 3 16 is -- 17 MR. ROTMAN: Can I have a copy of that, 18 please? 19 MR. KLATT: I'm sorry? 20 MR. ROTMAN: I'm waiting for a copy of 21 that. 22 MR. KLATT: Oh. Yes. We do provide 23 copies. 24 MR. ROTMAN: This is Exhibit No. 1? 25 THE WITNESS: I'm sorry. Which table?</p>
<p style="text-align: right;">Page 327</p> <p>1 not those heavy metals are in talc. I've looked 2 at some evidence that they are there, but I don't 3 have an opinion that they're actually in talc. 4 It's just another piece of evidence, again, for 5 the biological plausibility. 6 Q. Well, you're not saying that people who 7 regularly engage in chronic exercise, chronic 8 strenuous exercise, for a long period of time are 9 at increased risk of cancer because they have 10 increased gene expression, are you? 11 A. Well, there hasn't been epidemiologic 12 evidence that is consistent that people who do 13 routine strenuous exercise get cancer. 14 Q. The Buz'Zard study you cited, that 15 actually showed that talc -- increasing doses of 16 talc decreased release of reactive oxygen species 17 from ovarian cells, not increased it; correct? 18 A. I believe it was different -- I would 19 have to look at the study, but it was over 20 different time periods. It fluctuated. 21 Q. The highest level of reactive oxygen 22 species in the Buz'Zard study was the group of 23 cells that had no talc applied at all; correct? 24 A. I'd have to re-review the study. 25 Q. Let's --</p>	<p style="text-align: right;">Page 329</p> <p>1 MS. AHERN: Twenty-six. 2 BY MR. KLATT: 3 Q. Figure 3. Page 582. 4 MR. ROTMAN: What exhibit are we on? 5 COURT REPORTER: Twenty-six. 6 MR. ROTMAN: Thank you. 7 BY MR. KLATT: 8 Q. And you see Figure 3 is "ROS." 9 That stands for reactive oxygen species? 10 A. That's -- 11 Q. And, by the way, ROS are generated by 12 every cell of the body every day, 24 hours a day; 13 correct? 14 A. Reactive -- you do see it in daily cell 15 life. But, again, I'm talking about an 16 additional exposure, an agent that that is being 17 applied in addition to what you're seeing on -- 18 basically the cell has, as we just discussed, 19 they have ways of mitigating reactive oxygen 20 species. 21 The cell can increase their antioxidant 22 enzymes, but at some point, they can get 23 overloaded. So if you're giving it a higher dose 24 at a higher frequency than those systems can 25 handle, you're going to have an increased risk of</p>

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<p style="text-align: right;">Page 330</p> <p>1 mutagenesis.  2 Q. Well, let's look at what Buz'Zard found  3 when talc was applied to surface ovarian cells.  4 Do you see that? That's Figure 3A up at the  5 top?  6 A. A, up at the top. Yes.  7 Q. And you'll agree with me, you see on  8 the Y axis it says "Percentage of reactive oxygen  9 species generation in OSE2a cells"; correct?  10 A. Yes.  11 Q. That's ovarian surface epithelial  12 cells; correct?  13 A. Yes.  14 Q. And you'll see at the zero talc level  15 on the X axis --  16 A. Mm-hmm.  17 Q. -- that had 100 percent talc -- excuse  18 me -- a 100 percent reactive oxygen species  19 generation at all three time periods; correct?  20 A. That is correct. And --  21 Q. And when talc was applied?  22 MR. ROTMAN: Wait. Wait.  23 Did you finish your answer?  24 A. Well, we were just talking about how  25 cells can have innate ROS generation.</p>	<p style="text-align: right;">Page 332</p> <p>1 generation for each talc microgram.  2 Q. Do you see in the far right column,  3 they applied 200 micrograms of hydrogen peroxide?  4 A. Yes.  5 Q. And that resulted in a 200 percent  6 increase in reactive oxygen species during those  7 time periods; correct?  8 A. That is what it says. Yes.  9 Q. And that's their positive control;  10 correct?  11 A. Let me just double-check.  12 If I'm remembering the study correctly, yes,  13 you are -- you are right.  14 Q. People gargle with hydrogen peroxide;  15 correct?  16 A. They shouldn't.  17 Q. Well, you know, it's allowed on the  18 bottle.  19 You know that; correct?  20 A. If you're telling me they gargle with  21 it, that's fine.  22 Q. Well, they put it on cuts; right?  23 A. They shouldn't put it on cuts. It's  24 actually --  25 Q. It's sold for that, isn't it?</p>
<p style="text-align: right;">Page 331</p> <p>1 Q. And this graph shows that as you  2 applied increasing doses of talc, the level of  3 generation of reactive oxygen species in the  4 ovarian cells went down.  5 It didn't go up; correct?  6 A. Well, it goes up at -- what's the 50 --  7 the 50 micrograms per milliliter. It goes up at  8 that dose at the 120 hour, and then it goes up at  9 the 200 microgram level.  10 Q. That's not talc, is it?  11 A. I'm sorry. I'm looking at -- I'm  12 looking at -- it says "Talc micrograms per  13 milliliter," and then it lists the different  14 hours on the right; that they're color-coded to  15 the different hours.  16 Q. And 17 out of the 18 measurements they  17 took when talc is applied to ovarian cells showed  18 the ovarian cells generated less reactive oxygen  19 species than no talc at all; correct?  20 A. And I --  21 Q. Is that correct?  22 A. It looks like at different periods of  23 time at the 100 micrograms and 500, there was  24 less than the lower. But I'm not sure what the  25 threshold dose would be for optimal ROS</p>	<p style="text-align: right;">Page 333</p> <p>1 A. I think most MDs would tell you that  2 it's probably better not to use hydrogen peroxide  3 on open cuts because it can cause a pretty severe  4 reaction.  5 Q. You're aware that it's sold over the  6 counter in stores every day for -- as an  7 antiseptic?  8 A. Talcum powder is sold for everyday use  9 on babies.  10 Q. So are you telling us that hydrogen  11 peroxide now causes cancer?  12 A. I'm saying that it will release ROS  13 species generation.  14 Q. Far more than talc; correct?  15 A. Based on this study, it appears that  16 way.  17 Q. And you --  18 A. This one study.  19 Q. You agree with me this shows, as you  20 apply talc, reactive oxygen species in ovarian  21 cells decreases.  22 It doesn't increase at 17 out of 18 time  23 points; correct?  24 A. They're -- I will agree with you,  25 except there is a time point where it is</p>

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<p>1 increased. And I don't know -- my caveat is I 2 don't know where the threshold would be where the 3 ROS would stop being generated. 4 Q. Is aspirin approved by any 5 pharmaceutical company or recommended by any 6 medical organization for prevention of ovarian 7 cancer? 8 A. That is not on the label description. 9 Q. If aspirin prevented ovarian cancer, 10 don't you think it would be marketed for that 11 purpose? 12 MR. TISI: Objection. 13 MR. ROTMAN: Objection. 14 A. I'm sure it may be after years of FDA 15 red tape and approval, but the literature -- 16 again, I've said the literature is not as beefy 17 as the epi data when we're looking at aspirin and 18 NSAIDs. 19 NSAID, in particular, is not as consistent. 20 The aspirin data does appear to be consistent in 21 lowering the risk, but there are not a lot of 22 studies looking at this yet. 23 Again, though, just a piece of the puzzle 24 for a biologic plausibility. 25 Q. Well, certainly, we're not at the point</p>	<p>1 A. I have to look at the studies. There 2 might be one where it wasn't statistically 3 significant, but I think the majority of the ones 4 that looked at aspirin use showed a decreased 5 risk of ovarian cancer. 6 Q. Are you -- are you a member of the 7 International Society of Gynecologic 8 Pathologists? 9 A. I don't think I'm a member currently. 10 No. 11 Q. Have you ever been? 12 A. I believe so. 13 Q. It's not on your CV. 14 A. Okay. I'm not currently. I know that. 15 Q. Are you a member of the American 16 Society of Clinical Pathology? 17 A. I actually am. 18 Q. It's not on your CV. 19 A. Okay. That should be updated, then. 20 Q. Have you ever been a member of any 21 working group or organization on the 22 classification of female reproductive organ 23 tumors? 24 A. No. I can't -- no. 25 Q. You mentioned the Surgeon General's</p>
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<p>1 for aspirin and ovarian cancer that we are, for 2 example, with aspirin in terms of cardiovascular 3 risk; correct? 4 A. I would agree with that sentiment. 5 Q. And doctors and medical organizations 6 have recommended aspirin for reduction of 7 cardiovascular risk; correct? 8 A. That's correct. Although the dosage 9 has -- as of late, they're kind of parsing out 10 the -- they're reevaluating what dosages, but 11 you're correct. 12 Q. And you can't cite a single medical 13 organization that at this point in time says the 14 evidence that aspirin reduces ovarian cancer is 15 sufficient that women should take it on a regular 16 basis to reduce ovarian cancer; correct? 17 A. Well, I think I've said there aren't 18 that many studies yet. It's only -- that I'm 19 aware of, there are only a handful. They've been 20 consistent with aspirin. Not so much with NSAID. 21 That's, I think, as far as the evidence takes us 22 as this point. 23 Q. There's actually studies showing that 24 chronic aspirin ingestion doesn't decrease 25 ovarian cancer risk; correct?</p>	<p>1 report in 1964. You're aware that when that came 2 out about smoking, there were numerous studies in 3 the literature at that point in time showing that 4 the chemicals in cigarette smoke actually damaged 5 DNA and resulted in cancer; it wasn't based just 6 on epidemiology? 7 A. I think epidemiology -- my point was 8 that the epidemiology was the sort of first -- 9 there were pathologists that had noticed on 10 autopsies in patients that smoked -- it was 11 actually pathologists and a surgeon in the early 12 years -- that had noticed some changes, some 13 squamous metaplastic changes. 14 But it was really the epi data that sort of 15 drove the research on smoking and tobacco 16 initially. But, again, there were some studies 17 that had shown some pathologic changes in 18 smokers. That's true. 19 Q. You're aware that the cohort studies, 20 the hospital-based case-control studies, and the 21 population-based case-control studies all 22 uniformly showed that smoking increased the risk 23 of lung cancer; correct? 24 A. That's correct. 25 Q. And that's not true for talc and</p>

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<p>1 ovarian cancer; correct?</p> <p>2 A. Well, I have some issues with the</p> <p>3 cohort studies.</p> <p>4 Q. I know that.</p> <p>5 But my statement is true; correct?</p> <p>6 A. But I think it's relevant because the</p> <p>7 cohort studies, I don't believe, followed</p> <p>8 patients for a long enough time.</p> <p>9 The Nurses' Health Study only asked about</p> <p>10 talcum powder use once in 1982, so there's</p> <p>11 certainly room for misclassifications of users as</p> <p>12 never users.</p> <p>13 And some of -- some of -- again, there's</p> <p>14 smaller numbers because it's a -- it's a cohort</p> <p>15 study.</p> <p>16 Q. You're aware that the National Cancer</p> <p>17 Institute doesn't agree with you on that, aren't</p> <p>18 you?</p> <p>19 A. I have seen the NCI website. I</p> <p>20 certainly considered what they say about it. I</p> <p>21 don't know if they have done the same type of</p> <p>22 analysis as I've done. I don't believe it's on</p> <p>23 their website what methodology they used and what</p> <p>24 literature they reviewed.</p> <p>25 So I'm aware of what they've stated. But,</p>	<p>1 that one statement.</p> <p>2 Go ahead.</p> <p>3 MR. ROTMAN: If you want to do that,</p> <p>4 that's fine.</p> <p>5 BY MR. KLATT:</p> <p>6 Q. That draft -- Health Canada issued a</p> <p>7 draft assessment that's undergoing a 60-day</p> <p>8 public comment period; correct?</p> <p>9 A. That's true.</p> <p>10 Q. And then they have up to two years to</p> <p>11 decide whether to take any action or no action at</p> <p>12 all; correct?</p> <p>13 A. Well, there's two pieces of that. From</p> <p>14 my understanding is that they've already done the</p> <p>15 scientific. They've already done the literature</p> <p>16 review. They've already done their Bradford Hill</p> <p>17 analysis, and they've come to the conclusion that</p> <p>18 they've come to.</p> <p>19 And then there's the public commentary. And</p> <p>20 then there's the regulatory aspect of it.</p> <p>21 Now, I am -- I would not claim to be an</p> <p>22 expert in regulatory. I know we have regulatory</p> <p>23 experts that are coming on. But in -- from my</p> <p>24 understanding, the regulatory aspect is different</p> <p>25 than the scientific aspect.</p>
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<p>1 you know, I've still done this extensive review</p> <p>2 that I'm not sure they did to come to my</p> <p>3 conclusion.</p> <p>4 Q. You honestly don't know what the NCI</p> <p>5 did in terms of review to come to their</p> <p>6 conclusion, do you?</p> <p>7 A. They didn't state what they did, so I</p> <p>8 do not know. So that would -- but that's</p> <p>9 something that I'm thinking about when I'm taking</p> <p>10 into consideration.</p> <p>11 Q. And you are aware that they just</p> <p>12 updated their statement that the evidence does</p> <p>13 not support a link between talc and ovarian</p> <p>14 cancer in January 2019, the same month we're</p> <p>15 sitting here today?</p> <p>16 A. I don't know if I've gone to the NCI</p> <p>17 website this month.</p> <p>18 But I'm also aware of Health Canada that</p> <p>19 came out and did -- and we know what the</p> <p>20 methodology and literature they -- they spelled</p> <p>21 it out very clearly what their methodology was,</p> <p>22 what literature review they did, and they came to</p> <p>23 the same conclusion that I did.</p> <p>24 MR. ROTMAN: Off the record, Mike?</p> <p>25 MR. KLATT: Let me just follow up on</p>	<p>1 MR. ROTMAN: Mike, you're done? I just</p> <p>2 want to --</p> <p>3 MR. KLATT: I'm through.</p> <p>4 MR. ROTMAN: I just want to go off the</p> <p>5 record.</p> <p>6 We're done with seven hours.</p> <p>7 MR. KLATT: Yes. I'm done.</p> <p>8 MR. TISI: Let's take a minute.</p> <p>9 THE VIDEOGRAPHER: Off the record,</p> <p>10 6:31 p.m.</p> <p>11 (A recess was taken.)</p> <p>12 THE VIDEOGRAPHER: Back on the record,</p> <p>13 6:40 p.m.</p> <p>14 CROSS-EXAMINATION</p> <p>15 BY MR. ROTMAN:</p> <p>16 Q. Dr. Kane, I know it's been a long day</p> <p>17 for you, but I'm going to ask you a few</p> <p>18 questions. I will be brief.</p> <p>19 A. Okay.</p> <p>20 Q. At one point today, you were asked some</p> <p>21 questions by Attorney Ahern about certain</p> <p>22 negative studies on inflammation, and she</p> <p>23 mentioned Bonovast 2005 and Ni 2012, which she</p> <p>24 asked you about.</p> <p>25 Do you recall that?</p>

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<p style="text-align: right;">Page 342</p> <p>1 A. Yes.</p> <p>2 Q. She did not show you those studies, did</p> <p>3 she?</p> <p>4 A. I don't believe I saw them.</p> <p>5 Q. Are you able to agree with her</p> <p>6 characterization that these were negative studies</p> <p>7 without having -- without looking at them?</p> <p>8 A. I should have asked for them and had</p> <p>9 them in front of me while asking questions.</p> <p>10 Q. Now, you were asked questions --</p> <p>11 A. I mean answering questions.</p> <p>12 Q. -- throughout the day about</p> <p>13 inflammation as a biologically plausible</p> <p>14 mechanism for explaining talc causing ovarian</p> <p>15 cancer in light of the epi study findings.</p> <p>16 A. Yes.</p> <p>17 Q. You were also asked questions about</p> <p>18 cigarette smoking at various times throughout the</p> <p>19 day?</p> <p>20 A. Yes.</p> <p>21 Q. Does cigarette smoking have an</p> <p>22 inflammatory effect?</p> <p>23 A. Yes.</p> <p>24 Q. What is the --</p> <p>25 A. It does cause chronic inflammation.</p>	<p style="text-align: right;">Page 344</p> <p>1 just strike that.</p> <p>2 You were asked questions about surgical</p> <p>3 gloves and surgical-grade talc on surgical</p> <p>4 gloves.</p> <p>5 A. Yes.</p> <p>6 Q. Do you recall that?</p> <p>7 A. Yes.</p> <p>8 Q. And I think you were asked if you were</p> <p>9 aware of any studies linking the use of talcum</p> <p>10 powder on surgical gloves with the occurrence of</p> <p>11 ovarian cancer.</p> <p>12 Do you recall that?</p> <p>13 A. Yes.</p> <p>14 Q. Is there a difference, a notable</p> <p>15 difference, between talcum powder on surgical</p> <p>16 gloves and the talcum powder products in perineal</p> <p>17 use that, regardless of the constituent of the</p> <p>18 powder, that you would want to point out?</p> <p>19 MR. KLATT: Objection. Form.</p> <p>20 MS. AHERN: Same.</p> <p>21 A. So a patient's exposure to surgical</p> <p>22 gloves are going to be infrequent and not of long</p> <p>23 duration. It's not the same type of exposure as</p> <p>24 regular and frequent application of perineal</p> <p>25 talcum powder that we're seeing in the epi data.</p>
<p style="text-align: right;">Page 343</p> <p>1 Q. You were also asked questions about</p> <p>2 heavy metals being present in food and water and</p> <p>3 vitamins; correct?</p> <p>4 A. I remember. Yeah.</p> <p>5 Q. Do -- what is different between those</p> <p>6 circumstances and the situation that we have been</p> <p>7 discussing all day today involving talcum powder?</p> <p>8 A. With talcum powder, we do have the epi</p> <p>9 data that are consistent and show an increased</p> <p>10 risk of ovarian cancer with talcum powder use.</p> <p>11 Q. And with respect -- you were asked some</p> <p>12 questions in relation to the Buz'Zard study about</p> <p>13 hydrogen peroxide and the reactive oxygen species</p> <p>14 reaction?</p> <p>15 A. Yes.</p> <p>16 Q. Are you aware of any evidence that</p> <p>17 hydrogen peroxide -- the effect of hydrogen</p> <p>18 peroxide in the female genital tract?</p> <p>19 A. I'm not aware that women routinely use</p> <p>20 hydrogen peroxide in the female genital tract.</p> <p>21 Q. And is there anything in particular</p> <p>22 about the -- that part of the anatomy that where</p> <p>23 certain agents, exposure to certain agents, would</p> <p>24 raise any particular concerns -- strike that.</p> <p>25 I think that was a bad question, so I'll</p>	<p style="text-align: right;">Page 345</p> <p>1 MR. ROTMAN: No further questions.</p> <p>2 It's 6: --</p> <p>3 (Discussion off the record.)</p> <p>4 MR. ROTMAN: You're right.</p> <p>5 BY MR. ROTMAN:</p> <p>6 Q. I have some questions for you about</p> <p>7 your testimony on the Harlow paper.</p> <p>8 A. Okay.</p> <p>9 Q. Can you pull that out in front of you,</p> <p>10 which was Exhibit 20?</p> <p>11 A. Okay.</p> <p>12 Q. Can you turn to Table 3.</p> <p>13 A. Okay.</p> <p>14 Q. And do you recall that you were asked</p> <p>15 questions about dose-response in this study?</p> <p>16 A. Yes.</p> <p>17 Q. And do you recall that you were</p> <p>18 specifically asked questions about this Table 3?</p> <p>19 A. Yes.</p> <p>20 Q. Could you look at the middle part of</p> <p>21 Table 3, at the column with "adjusted odds</p> <p>22 ratios"?</p> <p>23 A. Yes.</p> <p>24 Q. What can -- what do you observe with</p> <p>25 respect to the adjusted odds ratio as the -- as</p>

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<p style="text-align: right;">Page 346</p> <p>1 the -- as the number of applications goes from 2 less than 1,000 to greater than 10,000? 3 A. The adjusted ORs go from -- the null, 4 1.0 at none, 1.4 at less than 1,000, to 1.7 at 5 greater than 10,000. 6 Q. And so what, just looking at the 7 adjusted odds ratio, what -- 8 A. It's an increase with increased -- 9 Q. -- what is your takeaway? 10 A. So it does show an increased odds ratio 11 with increased applications. 12 The confidence intervals do include the 13 null, but they're -- the higher end, it's higher 14 confidence interval at the upper end. 15 And it's not very far from the null on the 16 lower end. 17 And it, in fact, includes -- it's 1.0 at 18 greater than 10,000. 19 Q. And so for the 1,000 to 10,000 20 applications, the lower bound of the confidence 21 interval is .9? 22 A. Correct. 23 Q. And how close is that to being a 24 statistically significant finding? 25 A. Very close.</p>	<p style="text-align: right;">Page 348</p> <p>1 A. Yes. 2 Q. And this is -- this is in the 3 "Discussion" section of the paper; is that right? 4 A. Yes. 5 Q. And do you see in the paragraph that 6 I'm pointing to that begins with "Our study"? 7 A. Yes. 8 Q. Could you read into the record and 9 comment on the last sentence in that paragraph. 10 A. "Daily versus less-than-daily talc use 11 and talc use for more than ten years versus less 12 than ten years were associated with greater risk 13 for ovarian cancer." 14 Q. And can you comment on that? 15 A. So that does show a trend for a 16 dose-response. 17 MR. ROTMAN: Okay. So I have 6:48. 18 You've got eight minutes. 19 RECROSS-EXAMINATION 20 BY MR. KLATT: 21 Q. That Harlow study you were just looking 22 at -- 23 A. Yeah. 24 Q. -- is that the 1992 Harlow study? 25 A. It's the 1992 from Exhibit 20.</p>
<p style="text-align: right;">Page 347</p> <p>1 Q. And can you also take a look at the 2 discussion on that page in the left-hand column 3 in the paragraph that begins with "We also 4 examined"? 5 A. Okay. 6 Q. Is there a discussion in that paragraph 7 concerning the author's discussion of 8 dose-response? 9 A. Yeah. There's a sentence that states, 10 "The categorical analysis showed that relative to 11 nonusers, the risk was greatest in women who 12 applied talc at least once per day. When years 13 of use was included as a continuous variable, the 14 test for linear trend was 3.32, p-value of .07. 15 "The categorical analysis show that relative 16 to nonusers, women who applied talc for more than 17 ten years were at a 60 percent greater risk for 18 ovarian cancer. Likewise, perineal applications 19 of talc early in life, before age 20, or 20 applications within six months of diagnosis 21 reference age for controls produced the stronger 22 ORs." 23 Q. And I'd like to also call your 24 attention to the page 24 in the right-hand 25 column.</p>	<p style="text-align: right;">Page 349</p> <p>1 Q. And can you look on the last page of 2 this study, the page where the article ends and 3 the reference begins. 4 Did Harlow find the strength of association 5 between genital use of talc and ovarian cancer 6 was strong or weak? 7 A. So they use -- they say, "Because the 8 overall association between genital use of talc 9 and ovarian cancer remains weak." 10 And, again, "weak" is sort of a relative. 11 I've seen weak to moderate with this odds ratio. 12 And this is also 1992. 13 MR. KLATT: Object. Nonresponsive. 14 Q. I'm simply asking you, Dr. Kane, does 15 Harlow say strength of association between 16 ovarian cancer and talc use is strong or weak? 17 A. Well, I'm putting it in context. He 18 states -- I agree with you that's what the words 19 say, but I'm putting it in context in that "weak 20 to moderate" is used amongst epidemiologists for 21 this level of overall risk. 22 And this is 1992, so there wasn't the 23 subsequent studies that have gone on that show 24 consistent, similar overall risk odds ratio. 25 Q. And would it be correct that the</p>

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<p>1 statement that I asked you to read says in full, 2 "Because the overall association between genital 3 use of talc and ovarian cancer remains weak, it 4 is unlikely that this exposure disease pathway is 5 the principal one involved in ovarian cancer 6 etiology"? 7 Is that what Harlow said? 8 A. That's what it states. But, again, 9 that is 1992. This is the very beginning of the 10 epi data looking at this exposure and ovarian 11 cancer. 12 MR. KLATT: Object and move to strike 13 everything after "That's what it says." 14 Q. And, by the way, the odds ratio that 15 Harlow found overall was 1.5. 16 And that's even a little higher than the 17 odds ratios the more recent meta-analyses have 18 shown; correct? 19 A. So -- 20 Q. So they're even weaker than Harlow. 21 A. I'm sure some epidemiologists might 22 take -- I'm not -- but, again, I've seen, even 23 with 1.3 and 1.4, epidemiologists refer to that 24 as "moderate." 25 So I don't know if it's semantics, but it's</p>	<p>1 element of recall bias in case-control studies, 2 but the authors are aware. Many of them talk 3 about that and discuss why they feel recall bias 4 wasn't an explanation. 5 And, again, we're talking about multiple 6 studies over numerous populations over different 7 periods of time, most of them well before the 8 general public knew about an association between 9 talcum powder and ovarian cancer. 10 And even further, the fact that there's a 11 strong association in the literature with serous 12 invasive cancer would argue against a recall bias 13 because the lay public is not knowledgeable about 14 the histologic subtypes of epithelial ovarian 15 carcinoma. 16 Q. Let me ask you this, Dr. Kane: We 17 lawyers, before we have to go to trial, like to 18 know if the prospective jurors have already made 19 up their mind about the case. 20 Do you know if in any of these case-control 21 studies where the women who had ovarian cancer, 22 were they asked before they entered the study, 23 "Do you have a preconceived notion about what 24 caused your ovarian cancer?" 25 A. I'm not aware of a case-control design</p>
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<p>1 1.3. It's a 30 percent increased risk. In this 2 case, 1.5, a 50 percent increase in risk. And in 3 a rare disease like ovarian cancer, that's 4 significant. 5 Q. And Harlow calls a 1.5 odds ratio weak; 6 correct? 7 A. That's what he says in this 1992 paper. 8 Q. And you'd agree with me the more recent 9 meta-analyses of talc and ovarian cancer have a 10 lower odds ratio than 1.5? 11 A. They seem to be between 1.3 and 1.4, 12 but the important thing to me is the consistency. 13 Q. And you're aware that epidemiologists 14 say with case-control studies that odds ratios in 15 the range of 1.0 to 1.5 are well within the range 16 that can be explained by bias and confounding? 17 MR. ROTMAN: Objection. 18 A. I think all of the studies were 19 aware -- all of the authors were aware of 20 potential recall bias and confounding and sought 21 to control as much as possible those factors in 22 their control studies. Most of them, I feel, 23 were relatively well-designed to assess for and 24 adjust for multiple confounding factors. 25 And as far as recall bias, there's an</p>	<p>1 that would ask that question because even asking 2 that question would potentially add an element of 3 recall bias -- 4 Q. But if a woman already -- 5 MR. TISI: She wasn't finished. 6 Q. Were you finished? 7 A. I was going to say in a lot of these 8 studies, they also asked about smoking history 9 and other potential lifestyle issues in addition 10 to talcum powder use that would -- and yet, those 11 types of questions didn't show an elevated risk 12 like talcum powder products. 13 Q. Well, wouldn't you want to know -- 14 before you interviewed the women who have ovarian 15 cancer, wouldn't you want to know if they have a 16 preconceived notion about what caused their 17 ovarian cancer so if you didn't exclude them from 18 the study, at least you could take that 19 preconceived bias into account when you did the 20 statistics? 21 A. I would think if you're designing a 22 case-control study and trying to avoid recall 23 bias, there are better ways to do that because 24 just by asking, "Do you have a preconceived 25 notion about it?", you're introducing potential</p>

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<p>1 bias because they might think, Oh, maybe there is</p> <p>2 an association. And you're adding bias,</p> <p>3 potentially, that way.</p> <p>4 Q. You mentioned cigarette smoking just a</p> <p>5 minute ago in response to Mr. Rotman's questions.</p> <p>6 And you said cigarette smoking involves a</p> <p>7 chronic inflammatory condition in the body;</p> <p>8 correct?</p> <p>9 A. There is an inflammatory response in</p> <p>10 the body.</p> <p>11 Q. But cigarette smoking has not been</p> <p>12 shown to increase the risk of the two most common</p> <p>13 forms of ovarian cancer, which is serous invasive</p> <p>14 and endometrioid invasive; correct?</p> <p>15 A. So, again, different tissues will</p> <p>16 respond to different agents in different ways.</p> <p>17 Mucinous carcinoma has been associated in some</p> <p>18 studies with smoking, so there is evidence that</p> <p>19 epithelial ovarian cancer can be caused by</p> <p>20 smoking.</p> <p>21 MR. KLATT: Object. Nonresponsive.</p> <p>22 Q. The two most common forms of invasive</p> <p>23 ovarian cancer -- serous, which is the most</p> <p>24 common, and endometrioid, which is the second</p> <p>25 most common -- have not been shown to be elevated</p>	<p>1 Yes. It involves an inflammatory state.</p> <p>2 MR. KLATT: Thank you, Doctor.</p> <p>3 MR. TISI: Just one question.</p> <p>4 (Discussion off the record.)</p> <p>5 MR. ROTMAN: We're done.</p> <p>6 MR. TISI: Thank you.</p> <p>7 THE VIDEOGRAPHER: Here ends today's</p> <p>8 deposition. Off the record, 6:58 p.m.</p> <p>9 (Deposition concluded at 6:58 p.m.)</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
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<p>1 as a result of smoking; correct?</p> <p>2 A. The data has not shown an association</p> <p>3 between those two types with smoking.</p> <p>4 Q. Even though smoking involves a chronic</p> <p>5 inflammatory state; correct?</p> <p>6 A. But, again --</p> <p>7 Q. That is -- did you hear my question?</p> <p>8 Even though smoking involves a chronic</p> <p>9 inflammatory state; correct?</p> <p>10 A. We're talking about different types of</p> <p>11 exposures.</p> <p>12 Q. Does smoking --</p> <p>13 A. Different agent --</p> <p>14 MR. ROTMAN: One second, Mike.</p> <p>15 Do you want an answer to the question?</p> <p>16 Because you're cutting --</p> <p>17 BY MR. KLATT:</p> <p>18 Q. My question is: Does smoking</p> <p>19 involve --</p> <p>20 MR. ROTMAN: Wait. Wait, Mike. Let</p> <p>21 her answer the question, and then you're done</p> <p>22 because we're over.</p> <p>23 Do you know what the question was?</p> <p>24 A. Does smoking involve an inflammatory</p> <p>25 state?</p>	<p>1 -----</p> <p>2 E R R A T A</p> <p>3 -----</p> <p>4 PAGE LINE CHANGE</p> <p>5 REASON: _____</p> <p>6 _____</p> <p>7 REASON: _____</p> <p>8 _____</p> <p>9 REASON: _____</p> <p>10 _____</p> <p>11 REASON: _____</p> <p>12 _____</p> <p>13 REASON: _____</p> <p>14 _____</p> <p>15 REASON: _____</p> <p>16 _____</p> <p>17 REASON: _____</p> <p>18 _____</p> <p>19 REASON: _____</p> <p>20 _____</p> <p>21 REASON: _____</p> <p>22 _____</p> <p>23 REASON: _____</p> <p>24 _____</p> <p>25 REASON: _____</p>

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<p style="text-align: right;">Page 358</p> <p>1       ACKNOWLEDGMENT OF DEPONENT</p> <p>2</p> <p>3       I, _____, do</p> <p>4 hereby certify that I have read the</p> <p>5 foregoing pages, and that the same</p> <p>6 is a correct transcription of the answers</p> <p>7 given by me to the questions therein</p> <p>8 propounded, except for the corrections or</p> <p>9 changes in form or substance, if any,</p> <p>10 noted in the attached Errata Sheet.</p> <p>11</p> <p>12 _____</p> <p>13 SARAH E. KANE, M.D.       DATE</p> <p>14</p> <p>15 Subscribed and sworn</p> <p>16 to before me this</p> <p>17 _____ day of _____, 20____.</p> <p>18 My commission expires: _____</p> <p>19 _____</p> <p>20 Notary Public</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	
<p style="text-align: right;">Page 359</p> <p>1       C E R T I F I C A T E</p> <p>2       COMMONWEALTH OF MASSACHUSETTS</p> <p>3       SUFFOLK, SS.</p> <p>4       I, Janet M. Sambataro, a Registered Merit</p> <p>5 Reporter and a Notary Public within and for the</p> <p>6 Commonwealth of Massachusetts do hereby certify:</p> <p>7       THAT SARAH E. KANE, M.D., the witness whose</p> <p>8 testimony is hereinbefore set forth, was duly sworn</p> <p>9 by me and that such testimony is a true and accurate</p> <p>10 record of my stenotype notes taken in the foregoing</p> <p>11 matter, to the best of my knowledge, skill and</p> <p>12 ability; that before completion of the deposition</p> <p>13 review of the transcript was requested.</p> <p>14       I further certify that I am not related to any</p> <p>15 parties to this action by blood or marriage; and that</p> <p>16 I am in no way interested in the outcome of this</p> <p>17 matter.</p> <p>18       IN WITNESS WHEREOF, I have hereunto set my hand</p> <p>19 this 28th day of January, 2019.</p> <p>20</p> <p>21 _____</p> <p>22 JANET M. SAMBATARO</p> <p>23 Notary Public</p> <p>24 My Commission Expires:</p> <p>25 July 16, 2021</p>	

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# Exhibit 12

Robert Kurman, M.D.

Page 1

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NEW JERSEY

IN RE JOHNSON & JOHNSON :  
TALCUM POWDER PRODUCTS :  
MARKETING, SALES PRACTICES, AND :  
PRODUCTS LIABILITY LITIGATION :  
: NO. 16-2738  
: (FLW) (LHG)  
THIS DOCUMENT RELATES TO :  
ALL CASES :

- - -

APRIL 2, 2019

- - -

Videotaped deposition of ROBERT KURMAN, M.D.  
held in the offices of Duane Morris, LLP, 100 North City  
Parkway, Suite 1560, Las Vegas, Nevada, commencing at  
9:26 A.M., on the above date before Pamela Cotten, CSR,  
RDR, Certified Realtime Reporter, Certificate No. 4497.

- - -

GOLKOW LITIGATION SERVICES  
877.370.3377 ph | 917.591.5672 fax  
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Robert Kurman, M.D.

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Robert Kurman, M.D.

<p style="text-align: right;">Page 6</p> <p>1 EXHIBITS 2 (Continued) 3 Deposition Description Page 4 Exhibit 13 Article Titled "The Lack of 283 5 an Ovarian Effect of 6 Lifetime Talc Exposure in 7 F344/N Rats and B6C3F1 Mice" 8 9 Exhibit 14 Article Titled "Systematic 321 10 Review and Meta-Analysis of 11 the Association Between 12 Perineal Use of Talc and 13 Risk of Ovarian Cancer" by 14 Mohamed Kadry Taher, et al. 15 16 17 18 19 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 8</p> <p>1 MR. ZELLERS: Michael Zellers on behalf of the 2 Johnson &amp; Johnson defendants. 3 MS. AHERN: Hunter Ahern on behalf of Johnson &amp; 4 Johnson defendants. 5 VIDEO OPERATOR BROWN: The court reporter is Pam 6 Cotten, who will now swear in the witness. 7 8 ROBERT KURMAN, M.D., 9 called as a witness, and having been first duly sworn by 10 the Certified Shorthand Reporter, was examined and 11 testified as follows: 12 13 EXAMINATION 14 BY MR. DEARING: 15 Q Good morning, Doctor. 16 A Good morning. 17 Q We've met at least twice, I think. But I'm 18 David Dearing. I represent the plaintiffs in this 19 litigation, and I'm going to be asking you some 20 questions. 21 You've been produced as an expert by Johnson &amp; 22 Johnson in this case. So, first of all, if you would, 23 state your name, please. 24 A Robert Kurman. 25 Q What did you do to prepare for this</p>
<p style="text-align: right;">Page 7</p> <p>1 LAS VEGAS, NEVADA - TUESDAY, APRIL 2, 2019, 2 9:26 A.M. 3 VIDEO OPERATOR BROWN: Good morning. We are now on 4 the record. My name is Darnell Brown, and I'm the 5 videographer with Golkow Litigation Services. Today's 6 date is April 2nd, 2019, and the time is 9:26 A.M. 7 This video deposition is being held in 8 Las Vegas, Nevada, in the matter of In Re Talc for 9 United States District Court, Eastern District of New 10 Jersey. 11 The deponent is Dr. Robert Kurman. 12 Counsel, please identify yourselves for the 13 record. 14 MR. DEARING: David Dearing from Beasley Allen for 15 the plaintiffs. 16 MS. GARBER: Cynthia Garber, Robinson Calcagnie, 17 for the plaintiffs. 18 MR. ROTMAN: Steve Rotman, Hausfeld, for the 19 plaintiffs. 20 MR. BILLINGS-KANG: James Billings-Kang from 21 Seyfarth Shaw, Personal Care Products' counsel. 22 MR. ANDERTON: Michael Anderton, Tucker Ellis, for 23 PTI Royston and PTI Union. 24 MS. McBETH: Katherine McBeth, Drinker Biddle &amp; 25 Reath, on behalf of the Johnson &amp; Johnson defendants.</p>	<p style="text-align: right;">Page 9</p> <p>1 deposition? 2 A Well, you have to go back into my career. I 3 guess, in a way, I've been preparing for a long time, 4 so to speak. 5 I was a gynecologic pathologist for almost 6 40 years. And during the course of my career -- which 7 involves teaching and research and clinical care, 8 attending meetings, reviewing articles submitted to 9 journals -- I would be constantly reading the 10 literature in gynecologic pathology, which, of course, 11 included ovarian cancer. 12 Q Can I just cut you off. 13 What have you done in the last ten days to 14 prepare for this deposition? 15 A I've read over the defense -- the plaintiffs' 16 gynecologic pathology expert and gone over papers that 17 she's referred to. I've gone over my report and 18 perhaps googled a few things here and there. Oh, 19 PubMed, too. 20 Q Did you have meetings with Johnson &amp; Johnson 21 lawyers in preparation for this deposition? 22 A I did. 23 Q How much time have you spent with the 24 Johnson &amp; Johnson lawyers preparing for this 25 deposition?</p>

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<p style="text-align: right;">Page 10</p> <p>1 A I didn't keep track of the meetings per se --</p> <p>2 the time spent on the meetings per se.</p> <p>3 Q Can you estimate.</p> <p>4 A I hesitate not to estimate, since I'm under</p> <p>5 oath and I want to try to be as specific as possible.</p> <p>6 Q One of the advantages of being an expert is</p> <p>7 you're allowed to estimate. So can you give me a</p> <p>8 ballpark? Was it ten hours?</p> <p>9 MS. AHERN: Objection. Form.</p> <p>10 THE WITNESS: Maybe 15.</p> <p>11 BY MR. DEARING:</p> <p>12 Q Have you billed them for that time yet?</p> <p>13 A Some of it.</p> <p>14 (The document referenced below was</p> <p>15 marked Deposition Exhibit 1 for</p> <p>16 identification and is appended hereto.)</p> <p>17 BY MR. DEARING:</p> <p>18 Q I'm going to hand you a composite exhibit,</p> <p>19 which I've marked as Exhibit Number 1. And it is your</p> <p>20 report, your CV, and your reference list and the</p> <p>21 appendixes -- appendices with your report. So feel</p> <p>22 free to refer to that as much as you need to.</p> <p>23 I have copies for other people if anybody else</p> <p>24 wants a stack. I made six copies of everything. I</p> <p>25 hope we have enough.</p>	<p style="text-align: right;">Page 12</p> <p>1 BY MR. DEARING:</p> <p>2 Q It's okay if you haven't seen it; I just don't</p> <p>3 know.</p> <p>4 MR. DEARING: I'll just hand them to you, Cynthia,</p> <p>5 and you give them to anybody who wants it.</p> <p>6 MS. GARBER: I'll be your paralegal today.</p> <p>7 MR. DEARING: Thank you. Then we can trade if you</p> <p>8 want.</p> <p>9 THE WITNESS: No, I didn't see this.</p> <p>10 BY MR. DEARING:</p> <p>11 Q Okay. One of the things in this document that</p> <p>12 I just gave you, Exhibit 2, is a supplemental reference</p> <p>13 list, and it's the last four -- last three pages. It</p> <p>14 actually starts with page number 1 in the back of the</p> <p>15 document.</p> <p>16 Do you see that?</p> <p>17 A Yes.</p> <p>18 Q And at the very top, there's a list of</p> <p>19 reports.</p> <p>20 Do you see that list?</p> <p>21 A Yes.</p> <p>22 Q Those are all defense witnesses in this case,</p> <p>23 aren't they?</p> <p>24 A Yeah, it looks that way.</p> <p>25 Q Have you read all those reports?</p>
<p style="text-align: right;">Page 11</p> <p>1 BY MR. DEARING:</p> <p>2 Q So have you had a chance to just glance</p> <p>3 through what I just handed you?</p> <p>4 A Yes.</p> <p>5 Q Okay. And does that look like your report,</p> <p>6 your CV, your reference list, that kind of thing?</p> <p>7 A Yes.</p> <p>8 Q And did you write this report?</p> <p>9 A I sure did.</p> <p>10 (The document referenced below was</p> <p>11 marked Deposition Exhibit 2 for</p> <p>12 identification and is appended hereto.)</p> <p>13 BY MR. DEARING:</p> <p>14 Q Yesterday, I was given another document that</p> <p>15 I'm marking as Exhibit 2, and it's entitled</p> <p>16 "Defendants' Response to Plaintiffs' Document Requests</p> <p>17 Contained in Notice of Oral and Videotaped Deposition</p> <p>18 of Robert Kurman, M.D., and Duces Tecum."</p> <p>19 Have you ever seen this document before?</p> <p>20 MS. AHERN: Is that Exhibit 2?</p> <p>21 MR. DEARING: It's Exhibit 2, yes.</p> <p>22 THE WITNESS: This is what you showed me yesterday,</p> <p>23 isn't it? Is this what you showed me yesterday?</p> <p>24 MS. AHERN: Go ahead and take a look through it.</p> <p>25 And if you recognize it, you can let him know.</p>	<p style="text-align: right;">Page 13</p> <p>1 A No, I have not.</p> <p>2 Q Any idea why they would be on your reference</p> <p>3 list if you haven't read them?</p> <p>4 A They were offered to me, but I didn't read</p> <p>5 them all.</p> <p>6 Q Have you read any of them?</p> <p>7 A I did.</p> <p>8 Q Which ones have you read?</p> <p>9 A Dr. Michael Birrer, Dr. Jeff Boyd, Dr. Gregory</p> <p>10 Diette, Dr. Ie-Ming Shih, and Brooke Mossman.</p> <p>11 Q And I think you mentioned that you read the</p> <p>12 report of Dr. Kane; right?</p> <p>13 A I did.</p> <p>14 Q A plaintiff expert?</p> <p>15 A Yes.</p> <p>16 Q Did you read any other report of plaintiff</p> <p>17 experts?</p> <p>18 A No, I did not.</p> <p>19 Q Have you relied on any other materials that</p> <p>20 aren't contained in your original reference list or</p> <p>21 this new reference list that I got yesterday?</p> <p>22 A No, I have not.</p> <p>23 Q And for clarity, did you prepare this</p> <p>24 reference list that was handed to me yesterday?</p> <p>25 A I did not prepare that list.</p>

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<p style="text-align: right;">Page 14</p> <p>1 Q Did you ask someone to prepare that list?</p> <p>2 A No, I didn't.</p> <p>3 Q And the first time you saw it was this</p> <p>4 morning?</p> <p>5 A You asked me about this originally. I said I</p> <p>6 didn't see it. Honestly, I didn't look at the last</p> <p>7 three pages.</p> <p>8 Q Okay.</p> <p>9 A When you mention that, I did see that before,</p> <p>10 the reference list.</p> <p>11 Q Okay. But you didn't prepare it?</p> <p>12 A But I did not prepare it, no.</p> <p>13 Q Have you reviewed any internal corporate</p> <p>14 documents, emails, or testing data of Johnson &amp; Johnson</p> <p>15 and Imerys?</p> <p>16 A No, I haven't.</p> <p>17 Q As I understand it, you are now a retired</p> <p>18 gynecologic pathologist; is that right?</p> <p>19 A That's correct.</p> <p>20 Q Congratulations.</p> <p>21 A Thank you.</p> <p>22 Q And I understand that your medical license has</p> <p>23 lapsed as well; right?</p> <p>24 A I have a medical license in Nevada.</p> <p>25 Q Oh, you do?</p>	<p style="text-align: right;">Page 16</p> <p>1 able to say they were board-certified. They wanted to</p> <p>2 completely compete it -- excuse me -- completely</p> <p>3 confine it to pathologists. So they didn't approve of</p> <p>4 having a board specialty.</p> <p>5 Q But you can get board-certified in pathology;</p> <p>6 right?</p> <p>7 A Oh, certainly.</p> <p>8 Q Now, you've been deposed several times in this</p> <p>9 litigation; right?</p> <p>10 A A few times, yes.</p> <p>11 Q And you've actually testified in at least one</p> <p>12 trial; right?</p> <p>13 A Yes. I think you were the person that --</p> <p>14 Q It was me.</p> <p>15 Have you testified in any other trials?</p> <p>16 A No.</p> <p>17 Q And each time you testified, you took an oath</p> <p>18 to tell the truth, the whole truth; right?</p> <p>19 A Yes.</p> <p>20 Q And did you do that?</p> <p>21 A I did.</p> <p>22 Q And do you still stand by the testimony you</p> <p>23 gave previously in this litigation?</p> <p>24 MS. AHERN: Objection. Form.</p> <p>25 THE WITNESS: Well, I'd like to see what -- if</p>
<p style="text-align: right;">Page 15</p> <p>1 A I do.</p> <p>2 Q Do you agree with me that gynecologic</p> <p>3 pathology is not a recognized subspecialty of the</p> <p>4 American Board of Pathology?</p> <p>5 A Gynecologic pathology is a -- an acknowledged</p> <p>6 subspecialty that we have in virtually all major</p> <p>7 institutions, but it is not a board specialty.</p> <p>8 Q So you can't become board-certified in</p> <p>9 gynecologic pathology; correct?</p> <p>10 A Well, the point is that, in order to do expert</p> <p>11 work in gynecologic pathology, you need to really train</p> <p>12 in it, as your plaintiffs' expert did. But you don't</p> <p>13 need specific board certification.</p> <p>14 And, in fact, there was -- many years ago,</p> <p>15 there was -- and I was at the meeting. My predecessor</p> <p>16 at Hopkins, Dr. Don Woodruff, who was a gynecologist</p> <p>17 but had done a lot of gynecologic pathology -- in fact,</p> <p>18 he did the gynecologic pathology at Hopkins before I</p> <p>19 was there -- went to a meeting of the International</p> <p>20 Society of Gynecologic Pathologists and asked that it</p> <p>21 be made a board specialty.</p> <p>22 And the pathologists resisted. They didn't</p> <p>23 want to do it. The reason being that they were</p> <p>24 concerned that people like Dr. Woodruff -- with all</p> <p>25 respect to him -- they didn't want gynecologists to be</p>	<p style="text-align: right;">Page 17</p> <p>1 you're referring to specifically, I'd like to see it.</p> <p>2 But I told the truth then, and I'm telling the truth</p> <p>3 now.</p> <p>4 BY MR. DEARING:</p> <p>5 Q Do you believe your report is a fair and</p> <p>6 balanced statement of the science on the issues that</p> <p>7 you address?</p> <p>8 A I certainly do.</p> <p>9 Q When you wrote your report in this case, who</p> <p>10 was your intended audience or your intended reader?</p> <p>11 A I was responding specifically to the report of</p> <p>12 Dr. Kane, but I assumed that other individuals who were</p> <p>13 involved with this litigation would probably be reading</p> <p>14 it.</p> <p>15 Q Did you write it thinking that the judge would</p> <p>16 read it?</p> <p>17 A I assumed that that would eventually occur.</p> <p>18 Q When you were first contacted by Johnson &amp;</p> <p>19 Johnson regarding this talcum powder litigation, isn't</p> <p>20 it true that you had never researched the relationship</p> <p>21 between genital talc use and ovarian cancer?</p> <p>22 MS. AHERN: Objection. Form.</p> <p>23 THE WITNESS: Are you referring to when I was</p> <p>24 initially contacted or for this specific MDL?</p> <p>25 ///</p>

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<p style="text-align: right;">Page 18</p> <p>1 BY MR. DEARING:</p> <p>2 Q No. Before the MDL --</p> <p>3 A Okay.</p> <p>4 Q -- when Johnson &amp; Johnson first came to you,</p> <p>5 at that time, you had not researched the issue of</p> <p>6 genital talcum powder use and ovarian cancer; right?</p> <p>7 MS. AHERN: Objection. Form.</p> <p>8 THE WITNESS: That's correct, because amongst -- in</p> <p>9 pathologists in the community and gynecologists, as far</p> <p>10 as I know, there was never a question that talc was</p> <p>11 involved with ovarian cancer, so there was no need for</p> <p>12 me to really pursue it.</p> <p>13 BY MR. DEARING:</p> <p>14 Q Well, when was that that Johnson &amp; Johnson</p> <p>15 approached you to be a witness for them for the first</p> <p>16 time?</p> <p>17 A It was about 2015.</p> <p>18 Q So there was lots of literature out there and</p> <p>19 studies about the association or purported association</p> <p>20 between genital talc use and ovarian cancer; right?</p> <p>21 MS. AHERN: Objection. Form.</p> <p>22 THE WITNESS: They were epidemiology studies, which</p> <p>23 I think never rose to the level of being of interest to</p> <p>24 gynecologic pathologists -- gynecologic pathologists,</p> <p>25 for sure.</p>	<p style="text-align: right;">Page 20</p> <p>1 MS. AHERN: Objection. Misstates.</p> <p>2 THE WITNESS: I said before Johnson &amp; Johnson</p> <p>3 contacted me, there was, in the gynecologic pathology</p> <p>4 community, never -- never a question of talc being</p> <p>5 involved with ovarian cancer. So, therefore, I wasn't</p> <p>6 doing research on talc and ovarian cancer.</p> <p>7 BY MR. DEARING:</p> <p>8 Q Based on the research you've done since</p> <p>9 Johnson &amp; Johnson contacted you, you're aware that</p> <p>10 there are gynecologic pathologists who have published</p> <p>11 on this very topic, right, before Johnson &amp; Johnson</p> <p>12 contacted you; right?</p> <p>13 MS. AHERN: Objection. Form. Mischaracterizing</p> <p>14 the literature.</p> <p>15 BY MR. DEARING:</p> <p>16 Q William Welch at Harvard, for example, has</p> <p>17 published on this.</p> <p>18 He's a gynecologic pathologist; right?</p> <p>19 A I know Bill Welch quite well and --</p> <p>20 Q I'm just using him as an example.</p> <p>21 A Yeah, right. Right. In his -- he's on the</p> <p>22 paper, but I don't think he ever acknowledges that he</p> <p>23 says he supports talc as being a cause of ovarian</p> <p>24 cancer. I think he reviewed the pathology, and what</p> <p>25 his -- to make sure that these were whatever the</p>
<p style="text-align: right;">Page 19</p> <p>1 BY MR. DEARING:</p> <p>2 Q All those scientists that wrote those studies</p> <p>3 would be disappointed to hear you say that.</p> <p>4 But there were also animal studies, weren't</p> <p>5 there?</p> <p>6 MS. AHERN: Objection. Form.</p> <p>7 THE WITNESS: Maybe. I don't know.</p> <p>8 BY MR. DEARING:</p> <p>9 Q There were also cell studies, looking at the</p> <p>10 effects of talc on -- on cell structures and cells --</p> <p>11 MS. AHERN: Object.</p> <p>12 BY MR. DEARING:</p> <p>13 Q -- before Johnson &amp; Johnson contacted you;</p> <p>14 right?</p> <p>15 MS. AHERN: Objection. Form.</p> <p>16 THE WITNESS: As I said, I didn't -- as you -- I</p> <p>17 didn't read the literature on it before, so I have</p> <p>18 no -- no idea.</p> <p>19 BY MR. DEARING:</p> <p>20 Q So when you -- I don't want to put words in</p> <p>21 your mouth.</p> <p>22 Did you say that, before Johnson &amp; Johnson</p> <p>23 contacted you, it wasn't important to you?</p> <p>24 I don't remember what you said.</p> <p>25 A I--</p>	<p style="text-align: right;">Page 21</p> <p>1 authors were saying were ovarian cancers.</p> <p>2 Q My point is, before Johnson &amp; Johnson</p> <p>3 contacted you to be one of their experts, there was</p> <p>4 some interest among some gynecologic pathologists about</p> <p>5 this issue of talc and ovarian cancer, right --</p> <p>6 MS. AHERN: Objection. Form.</p> <p>7 BY MR. DEARING:</p> <p>8 Q -- as evidenced by the publications that they</p> <p>9 put their name on?</p> <p>10 MS. AHERN: Objection. Form.</p> <p>11 THE WITNESS: As I said, Bill Welch, who I honestly</p> <p>12 didn't speak to specifically about this topic, but I</p> <p>13 can -- at meetings, he's never brought it up. So I</p> <p>14 assumed -- assume.</p> <p>15 I should say that, based on those</p> <p>16 publications, I -- he reviewed those cases. He said</p> <p>17 they were ovarian cancers, but I don't know if there's</p> <p>18 any evidence that he indicated that he believed that</p> <p>19 talc caused ovarian cancer.</p> <p>20 BY MR. DEARING:</p> <p>21 Q And you understand I'm not talking about just</p> <p>22 Dr. Welch.</p> <p>23 I'm talking about other gynecologic</p> <p>24 pathologists have contributed to papers, studies on the</p> <p>25 issue of talc and ovarian cancer before Johnson &amp;</p>

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<p style="text-align: right;">Page 22</p> <p>1 Johnson came to you and hired you as an expert; right?</p> <p>2 MS. AHERN: Objection. Form.</p> <p>3 BY MR. DEARING:</p> <p>4 Q Are you aware of those papers?</p> <p>5 A You'll have to show them to me.</p> <p>6 Q Okay.</p> <p>7 A Please.</p> <p>8 Q Okay. So none come to mind, as we sit here?</p> <p>9 A You'll have to show them to me.</p> <p>10 Q Okay. And would you also agree that, before</p> <p>11 Johnson &amp; Johnson hired you, many other scientists in</p> <p>12 other fields were quite interested in the issue of</p> <p>13 genital talc use and ovarian cancer and were publishing</p> <p>14 on it?</p> <p>15 MS. AHERN: Objection. Form.</p> <p>16 THE WITNESS: As I said, since I did not research</p> <p>17 the area of talc use and the possible talc exposure to</p> <p>18 the development of ovarian cancer prior to the time</p> <p>19 that Johnson &amp; Johnson contacted me, I wasn't aware of</p> <p>20 those studies.</p> <p>21 BY MR. DEARING:</p> <p>22 Q All right. But since then, since you've been</p> <p>23 hired by Johnson &amp; Johnson, you've done a lot of</p> <p>24 research on it and you've seen that studies were</p> <p>25 published long before Johnson &amp; Johnson hired you, even</p>	<p style="text-align: right;">Page 24</p> <p>1 mean?</p> <p>2 A Well, there may -- if there was a study that</p> <p>3 had -- if there was some kind of exposure to talc that</p> <p>4 I was looking under the microscope, I would assume that</p> <p>5 it would -- that it would create a foreign-body giant</p> <p>6 cell granulomatous inflammation. And I would,</p> <p>7 therefore, have polarized it, perhaps looked at that</p> <p>8 that way. But it haven't seen that.</p> <p>9 MR. DEARING: Okay. Move to strike as</p> <p>10 nonresponsive.</p> <p>11 BY MR. DEARING:</p> <p>12 Q My question is, have you looked at talc or</p> <p>13 Johnson &amp; Johnson body powder products under a</p> <p>14 microscope?</p> <p>15 A I have not looked at talc, Johnson &amp; Johnson</p> <p>16 products, as far as I know, under the microscope.</p> <p>17 Q Have you ever studied gynecologic tissue --</p> <p>18 I'm sorry. Strike that.</p> <p>19 Have you ever studied talc in gynecologic</p> <p>20 tissue under a microscope, you specifically?</p> <p>21 A I thought I just answered that question.</p> <p>22 Isn't that what you just asked me?</p> <p>23 Q No. I asked if you looked at the powder. Now</p> <p>24 I'm asking you about tissue.</p> <p>25 A Oh. So your first question was talc powder</p>
<p style="text-align: right;">Page 23</p> <p>1 as far back as the '70s, on this very topic; right?</p> <p>2 A I've seen, since my research on the subject,</p> <p>3 yes, that there have been studies that were performed</p> <p>4 before 2015.</p> <p>5 Q And you've never published on the topic of</p> <p>6 talc and ovarian cancer; correct?</p> <p>7 A No, I have not.</p> <p>8 Q And you've never lectured on it?</p> <p>9 A I have never lectured on it.</p> <p>10 Q Have you ever studied talc, and specifically</p> <p>11 Johnson &amp; Johnson's baby powder or Shower to Shower</p> <p>12 product, under a microscope?</p> <p>13 MS. AHERN: Objection. Form.</p> <p>14 THE WITNESS: I have not specifically done a study</p> <p>15 looking at talc exposure in tissues under the</p> <p>16 microscope.</p> <p>17 BY MR. DEARING:</p> <p>18 Q Have you even looked at just plain talc under</p> <p>19 a microscope?</p> <p>20 A Not specifically, no, I have not.</p> <p>21 Q Have you looked at it nonspecifically?</p> <p>22 What do you mean by that?</p> <p>23 MS. AHERN: Objection. Form.</p> <p>24 BY MR. DEARING:</p> <p>25 Q When you say "not specifically," what do you</p>	<p style="text-align: right;">Page 25</p> <p>1 not being in tissue?</p> <p>2 Q Right. My first question didn't mention</p> <p>3 tissue at all.</p> <p>4 Do you need me to ask it again?</p> <p>5 A Well, certainly. I don't look at -- I look at</p> <p>6 tissue. I never look at things that are not tissue.</p> <p>7 Q Okay. You don't think it's important to look</p> <p>8 at the morphology and characteristics of talc by itself</p> <p>9 in order to assist you in looking at talc in tissue?</p> <p>10 A No. If I see it in tissue, I'd recognize it,</p> <p>11 as I mentioned with polarization. Seeing a</p> <p>12 foreign-body giant cell reaction, polarizing it there,</p> <p>13 seeing birefringent particles, might be talc.</p> <p>14 Q Have you studied talc in gynecologic tissue</p> <p>15 under a microscope?</p> <p>16 A Okay. So now we are talking about tissue.</p> <p>17 Q Yeah.</p> <p>18 A I have not.</p> <p>19 Q And you just said that you could look at talc</p> <p>20 in tissue and recognize it by polarized light.</p> <p>21 Isn't it true that you hardly ever do that?</p> <p>22 MS. AHERN: Objection. Form.</p> <p>23 BY MR. DEARING:</p> <p>24 Q In fact, I think those were your actual words,</p> <p>25 that you hardly ever do that.</p>



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<p style="text-align: right;">Page 26</p> <p>1 A Well, let me describe the situation to you. I</p> <p>2 don't routinely look at tissue using polarized light.</p> <p>3 There's got to be an indication.</p> <p>4 The indication is, do I see a foreign-body</p> <p>5 giant cell reaction? Then I would say, "Ah, there may</p> <p>6 be something here that's polarizable." Then I would</p> <p>7 polarize it.</p> <p>8 Q That doesn't happen very often, does it?</p> <p>9 A It does not happen very often.</p> <p>10 Q Have you ever participated in any lab study of</p> <p>11 cellular reaction to talc exposure?</p> <p>12 A I haven't --</p> <p>13 MS. AHERN: Objection. Form.</p> <p>14 THE WITNESS: I have not participated. I'm not a</p> <p>15 laboratory scientist. I'm not a bench scientist. I'm</p> <p>16 a surgical pathologist.</p> <p>17 BY MR. DEARING:</p> <p>18 Q And you're not qualified to perform analytical</p> <p>19 scanning electron microscopy or transmission electron</p> <p>20 microscopy or Raman spectroscopy, are you?</p> <p>21 A Those techniques are not those -- I don't use</p> <p>22 those techniques.</p> <p>23 Q You've served on many peer review and</p> <p>24 editorial committees for a variety of journals and</p> <p>25 professional publications.</p>	<p style="text-align: right;">Page 28</p> <p>1 decides how to respond to those comments. And then</p> <p>2 that's resubmitted to the -- to the editor. And then</p> <p>3 the editor, again, makes a decision. Did these authors</p> <p>4 provide enough explanation to now have successfully</p> <p>5 addressed the concerns of the reviewers? Or, hmm,</p> <p>6 maybe not, in which case they might send it back to the</p> <p>7 reviewers and ask them again to review the paper.</p> <p>8 And it goes through the same process again of</p> <p>9 the reviewers saying, well, yes, they have addressed</p> <p>10 the questions, or, no, they haven't addressed the</p> <p>11 questions and, therefore, again submit their</p> <p>12 recommendation to the editor.</p> <p>13 Q And that's been your experience and your own</p> <p>14 participation either by submitting general publications</p> <p>15 for publication or serving on these review committees?</p> <p>16 A Yes.</p> <p>17 Q And would you agree that the primary purpose</p> <p>18 of the peer review process is to validate proposed</p> <p>19 scientific findings, methodologies, opinions, and</p> <p>20 hypotheses so that bad science doesn't get published in</p> <p>21 journals?</p> <p>22 MS. AHERN: Objection. Form.</p> <p>23 THE WITNESS: The responsibility of the reviewers</p> <p>24 is to perform a fair review of the science and</p> <p>25 determine whether that science has been -- is</p>
<p style="text-align: right;">Page 27</p> <p>1 Can you describe how that peer review process</p> <p>2 typically works?</p> <p>3 A Sure. Paper's submitted to a journal. The</p> <p>4 editor looks it over and determines, among the people</p> <p>5 on the editorial board or people not necessarily on the</p> <p>6 editorial board, who has the necessary expertise or</p> <p>7 interest in the area to review the paper and provide a</p> <p>8 commentary on it, pointing out whether the paper is</p> <p>9 acceptable as submitted or are there problems with it</p> <p>10 that need to be addressed by the authors.</p> <p>11 So that reviewer then submits a report back to</p> <p>12 the editor. The editor reviews it, looks at it, one</p> <p>13 reviewer's comments -- and invariably it is sent to</p> <p>14 more than one reviewer -- and compares the review of</p> <p>15 one reviewer to the review of another.</p> <p>16 If they're concordant the editor, based on</p> <p>17 that editor's judgment, would probably agree and say,</p> <p>18 based on these reviewers' comments, I will either</p> <p>19 accept the paper, I will reject it out of hand, or I</p> <p>20 will resubmit it to the authors and say it's -- the</p> <p>21 reviewers have deemed that your paper is acceptable</p> <p>22 with the provision that you address certain specific</p> <p>23 issues. And those issues are listed for the -- for the</p> <p>24 author to look at.</p> <p>25 And the author reviews those comments and then</p>	<p style="text-align: right;">Page 29</p> <p>1 appropriate -- is reliable, is valid, and, therefore,</p> <p>2 agree or disagree, as I said earlier, to either reject</p> <p>3 or accept the paper.</p> <p>4 BY MR. DEARING:</p> <p>5 Q None of the opinions that you're offering</p> <p>6 today regarding talc and ovarian cancer have ever been</p> <p>7 published or have ever gone through any peer review</p> <p>8 process, have they?</p> <p>9 A That's correct.</p> <p>10 Q Have you tried to publish your opinions about</p> <p>11 talc and ovarian cancer?</p> <p>12 A No, I have not.</p> <p>13 Q When Johnson &amp; Johnson first approached you</p> <p>14 for serving as an expert witness in the MDL litigation</p> <p>15 that we are here about today, what's your understanding</p> <p>16 of what they wanted you to do?</p> <p>17 A Well, it was my impression from speaking with</p> <p>18 them that the primary -- what my primary function was,</p> <p>19 really, was to be an expert in gynecologic pathology,</p> <p>20 which I am, I think, and go over the issues of ovarian</p> <p>21 carcinogenesis from the standpoint of surgical</p> <p>22 pathology and to review the data concerning talc</p> <p>23 exposure and possible involvement in the development of</p> <p>24 ovarian cancer in terms of ovarian carcinogenesis</p> <p>25 causation and to review the plaintiffs' expert</p>

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<p style="text-align: right;">Page 30</p> <p>1 gynecologic pathologist's report.</p> <p>2 Q And when you say "review the data," are you</p> <p>3 talking about cell study data or are you talking about</p> <p>4 epidemiology? What are you referring to?</p> <p>5 A Well, specifically -- not epidemiologic data</p> <p>6 because I testified to that before, but I'm not an</p> <p>7 epidemiologist. So it was -- really, the interest was</p> <p>8 in my expertise in gynecologic pathology with the</p> <p>9 focus, again, being on the -- my work as a gynecologic</p> <p>10 pathologist. As I said, I'm not a bench scientist. I</p> <p>11 can certainly review some of those papers, but my area</p> <p>12 and expertise is surgical pathology.</p> <p>13 Q Is it fair to say that, if there are studies</p> <p>14 out there pertaining to talc and ovarian cancer that</p> <p>15 are not on your reference list, that you've not</p> <p>16 reviewed them?</p> <p>17 MS. AHERN: Objection. Form.</p> <p>18 THE WITNESS: I may have seen other papers that</p> <p>19 I've looked at but didn't decide, for whatever reason,</p> <p>20 to specifically -- there's a huge -- you know, there</p> <p>21 are a lot of papers out there that I may have even</p> <p>22 missed. So there may be some things out there that I'm</p> <p>23 not aware of that I didn't include.</p> <p>24 BY MR. DEARING:</p> <p>25 Q Since epidemiology is not your specialty, is</p>	<p style="text-align: right;">Page 32</p> <p>1 Q Sure. There are several on the second one</p> <p>2 that I got yesterday, but right now I'm asking you</p> <p>3 about the first one.</p> <p>4 A Okay. Well, for starters, Camargo, I believe,</p> <p>5 may have been an epidemiologic study.</p> <p>6 Q Can you refer me to what page?</p> <p>7 A Oh, I'm looking at page 12 of the references,</p> <p>8 Number 9, Camargo.</p> <p>9 Q Okay.</p> <p>10 A There are a couple of papers by Dan Cramer, 14</p> <p>11 and 15, which are epidemiologic studies, one -- 15, in</p> <p>12 fact, was published in an epidemiology journal.</p> <p>13 Number 23, Falconer in "Ovarian Cancer Risk</p> <p>14 After Salpingectomy: A Nationwide Population-Based</p> <p>15 Study."</p> <p>16 Q Let me ask a question in a different way, if I</p> <p>17 can.</p> <p>18 A Okay.</p> <p>19 Q Certainly lots of these studies rely on</p> <p>20 population data.</p> <p>21 Did you rely on any of the population data or</p> <p>22 findings of epidemiology studies in preparing your</p> <p>23 report and the opinions within your report?</p> <p>24 A Well, as I've said, I've indicate I -- earlier</p> <p>25 on in the litigation, I have reviewed -- I reviewed</p>
<p style="text-align: right;">Page 31</p> <p>1 it fair to say that you've not considered the complete</p> <p>2 body of literature in epidemiology on the issue of talc</p> <p>3 and ovarian cancer?</p> <p>4 A No, no, I wouldn't say that at all. I've</p> <p>5 looked at those epidemiology papers, and even though</p> <p>6 I'm not an epidemiologist, I can get a -- I can</p> <p>7 understand them. I'm not an expert in epidemiology,</p> <p>8 but their papers are important, and I reviewed them.</p> <p>9 Q Right. And if you reviewed them, are they</p> <p>10 identified on your reference materials list, either the</p> <p>11 first one or the one I got yesterday?</p> <p>12 A I imagine that some of them are. I'd have to</p> <p>13 look specifically.</p> <p>14 Q Okay. Well, I didn't see any epidemiology</p> <p>15 studies on the first list I was provided with your</p> <p>16 original report. You're welcome to look at it. It's</p> <p>17 right in front of you. But does that sound right? I'm</p> <p>18 not going to spend a lot of time on it.</p> <p>19 MS. AHERN: Are you talking about his reference</p> <p>20 list from his report?</p> <p>21 BY MR. DEARING:</p> <p>22 Q Right. I didn't recognize any epidemiology</p> <p>23 studies --</p> <p>24 A Well, I'd have to go through the reference</p> <p>25 list and look at them, actually. Can I do that?</p>	<p style="text-align: right;">Page 33</p> <p>1 many of these studies, the epidemiologic studies. I</p> <p>2 briefly looked at them again -- over again and didn't</p> <p>3 see any reason that they brought -- changed my</p> <p>4 testimony from what I've done in the past.</p> <p>5 So, yes, I have looked at them and I've taken</p> <p>6 them into account.</p> <p>7 Q Do you think you have reviewed epidemiology</p> <p>8 studies on this topic of talc and ovarian cancer that</p> <p>9 aren't reflected in your reference list?</p> <p>10 A I may have, yes.</p> <p>11 Q Have you reviewed the Terry study?</p> <p>12 A Terry study, no, does not sound familiar.</p> <p>13 Q Have you reviewed the Taher study, T-a-h-e-r?</p> <p>14 A I'd have to see that one. I might have. Do</p> <p>15 you have it?</p> <p>16 Q I do. We're going to come back to it in a</p> <p>17 little bit. I'm just trying to get a --</p> <p>18 A At this point, I won't comment. I'd like to</p> <p>19 see it. I may have.</p> <p>20 Q You may have?</p> <p>21 A Yeah.</p> <p>22 Q How about Penninkilampi? Have you looked at</p> <p>23 that study?</p> <p>24 A I looked at the abstract.</p> <p>25 Q On page 12 of your report -- and I think you</p>

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<p>1 sort of just said this -- you say that "Although 2 Dr. Kane offers opinions in a host of areas outside of 3 her field, including epidemiology and cancer biology, I 4 will focus my report on the primary area of" -- 5 A Excuse me. Could you tell me exactly where 6 you are reading from? 7 Q Sure. Page 12. 8 A Yeah, I got that. 9 Q At the top. First paragraph. 10 A Okay. 11 Q Last sentence. 12 A Okay. 13 Q "Although Dr. Kane offers opinions 14 in a host of areas outside her field, 15 including epidemiology and cancer 16 biology, I will focus my report on my 17 primary area of expertise, gynecologic 18 pathology." 19 So I want to ask you about that statement. 20 Does that mean that you only intend to testify 21 about gynecologic pathology, and not epidemiology and 22 cancer biology? 23 MS. AHERN: Objection. Form. Depends what you ask 24 him. 25 MR. DEARING: He seems to be defining the</p>	<p>1 MS. AHERN: Objection. Form. 2 THE WITNESS: Pretty much so, yes. 3 BY MR. DEARING: 4 Q Are you intending to offer any opinions that 5 are not contained in your report? 6 MS. AHERN: Objection. Form. 7 THE WITNESS: I'd have to hear the question, but I 8 don't think I would. 9 BY MR. DEARING: 10 Q Was it your idea to add the 16 defense experts 11 to your second reference list -- 16 expert reports? 12 A No. 13 MS. AHERN: David, can I just quickly -- it might 14 help a little bit. We put together the reference list 15 which contains any materials we provided to him, should 16 he want to review them, and also includes articles I 17 think he found himself that he's reviewed. 18 So we tried to give you a complete list of 19 everything that he had to consider. You'll have to ask 20 him if he actually reviewed it. 21 BY MR. DEARING: 22 Q The only plaintiff expert report you reviewed 23 was Dr. Kane's; right? 24 A Correct. 25 Q Are the opinions of the other defense experts</p>
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<p>1 parameters of his testimony. So I want to know what 2 he's comfortable with testifying about. 3 MS. AHERN: Understood. 4 THE WITNESS: As I said, that is my primary focus. 5 An epidemiology study that may touch on it briefly, I 6 could mention, but it isn't what I'm focusing my 7 specific testimony on. 8 BY MR. DEARING: 9 Q So, as you sit here today, it is not your 10 intention to dissect epidemiology studies? 11 A That's correct. 12 Q And it is not your intention to offer 13 testimony on cancer biology? 14 MS. AHERN: Objection. Form. 15 BY MR. DEARING: 16 Q Right? 17 A That's correct. 18 Q Does your report contain a complete outline of 19 your opinions? 20 MS. AHERN: Objection. Form. 21 THE WITNESS: What do you mean by a "complete 22 outline" of my opinions? 23 BY MR. DEARING: 24 Q Does your report contain a complete statement 25 of your opinions regarding talc and ovarian cancer?</p>	<p>1 in this case relevant to your pathology opinions? 2 A Well, I didn't read them. So I can't comment 3 on them. 4 Q But if you thought they were relevant, you 5 would have read them; right? 6 A Since they weren't pathologists and my focus 7 was on the pathology, I -- I would think that's 8 correct. I would focus on pathology. 9 Q Certainly your pathology opinions are not 10 dependent on the opinions of the other defense experts; 11 right? 12 A Well, again, I'd have to see -- if you're 13 referring to something specifically, I would like to 14 see what it is. But, in general, they're not -- it's 15 not focused -- if they don't discuss pathology, it is 16 not relevant to my testimony. 17 Q Since your report was written long before 18 yesterday when I received your supplemental reference 19 list, is it fair to say that none of the opinions in 20 your report are dependent upon anything that's on the 21 reference list that I was provided yesterday? 22 A That's correct. 23 Q Do any of the materials I was recently 24 provided on your second reference list influence or 25 affect or change any of the opinions that you've</p>

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<p style="text-align: right;">Page 38</p> <p>1 already put in your report?</p> <p>2 A Let me look at that reference list again.</p> <p>3 Well, I don't know if I mentioned it. I did</p> <p>4 read -- oh, I did mention it earlier. I read</p> <p>5 Dr. Shih's deposition, and it included a report of his,</p> <p>6 a study he was doing. I read that. But I mentioned</p> <p>7 that before.</p> <p>8 Other than that, no. I mean, obviously, the</p> <p>9 Jeff Seidman study, I was an author. I'm involved with</p> <p>10 that paper on papillary tubal hyperplasia. I wrote it,</p> <p>11 so I know that.</p> <p>12 I would say, yes, actually, looking at it,</p> <p>13 there was an important paper that is listed on</p> <p>14 page 2 -- important in my opinion -- by -- it is the</p> <p>15 second one from the top. Ducie, H. et al., which I</p> <p>16 would -- it's not in my original report, but I would --</p> <p>17 I might refer to that.</p> <p>18 Q I believe the question was did your review any</p> <p>19 of the materials on the supplemental reference list</p> <p>20 affect or change any opinions --</p> <p>21 A Oh.</p> <p>22 Q -- you've already written in your report?</p> <p>23 A No, it does not change my opinion.</p> <p>24 Q If you are not intending to offer epidemiology</p> <p>25 opinions or discuss the underlying data of epidemiology</p>	<p style="text-align: right;">Page 40</p> <p>1 disclosure of what he might have reviewed in</p> <p>2 preparation for the deposition. We were just</p> <p>3 overinclusive.</p> <p>4 MR. DEARING: Thank you.</p> <p>5 BY MR. DEARING:</p> <p>6 Q Did you read any of these studies that are on</p> <p>7 the supplemental list?</p> <p>8 A Again, as I mentioned --</p> <p>9 Q You read one of them, but --</p> <p>10 A -- in the past when I did discuss epidemiology</p> <p>11 in greater detail, I have read Gates, Gertig.</p> <p>12 Gonzalez, I actually might have looked at more</p> <p>13 recently. Houghton, I've looked at in the past. I</p> <p>14 mentioned Penninkilampi.</p> <p>15 Q Are you prepared to discuss those studies</p> <p>16 today?</p> <p>17 A Well, as I said, I looked in the past. I</p> <p>18 haven't really recently gone over them in depth. If</p> <p>19 there's some specific question you may want to ask, I</p> <p>20 could look at it. But the focus of my testimony is not</p> <p>21 on the epidemiology, as we've discussed.</p> <p>22 Q I want to try today to keep you within your</p> <p>23 field of expertise, and I don't want to drag you out in</p> <p>24 any other area that you're not comfortable in or you</p> <p>25 don't feel qualified in. So if I do that, please tell</p>
<p style="text-align: right;">Page 39</p> <p>1 studies, why did you add about 15 epidemiology studies</p> <p>2 in your supplemental list for today's deposition?</p> <p>3 MS. AHERN: Objection. Form.</p> <p>4 BY MR. DEARING:</p> <p>5 Q Or was your testimony you didn't add those;</p> <p>6 someone else did?</p> <p>7 A Yes.</p> <p>8 Q Okay.</p> <p>9 A They were provided to me. If I was of</p> <p>10 interest to read them, I could read them. But I didn't</p> <p>11 read them.</p> <p>12 Q Okay.</p> <p>13 A I did mention I did look at the abstract of</p> <p>14 Penninkilampi.</p> <p>15 Q Do you think you read any of the epidemiology</p> <p>16 studies that are in the supplemental list?</p> <p>17 A Let me take a look.</p> <p>18 MS. AHERN: You mean recently or previously?</p> <p>19 BY MR. DEARING:</p> <p>20 Q They're in a reliance list. So did you read</p> <p>21 any anticipating you might review on them?</p> <p>22 MS. AHERN: Well, I would object to the</p> <p>23 characterization this is a reliance list. This is a</p> <p>24 supplemental list of materials that we either provided</p> <p>25 to him or he selected himself so that you had full</p>	<p style="text-align: right;">Page 41</p> <p>1 me. Okay?</p> <p>2 A Okay.</p> <p>3 MS. AHERN: Objection.</p> <p>4 BY MR. DEARING:</p> <p>5 Q Based on your research that you've done in</p> <p>6 your entire career, both before and after Johnson &amp;</p> <p>7 Johnson hired you as an expert in this case and in this</p> <p>8 litigation, in general, years ago, would you agree with</p> <p>9 me that there are about 30 or so epidemiology studies</p> <p>10 on talc and ovarian cancer that are not on either of</p> <p>11 your reference lists?</p> <p>12 MS. AHERN: Objection. Form.</p> <p>13 THE WITNESS: I'd have to go over and look all</p> <p>14 these 30 that you mentioned. So I can't really</p> <p>15 comment.</p> <p>16 BY MR. DEARING:</p> <p>17 Q As you sit here now, would you agree that your</p> <p>18 two reference lists do not include all of the</p> <p>19 epidemiology studies, not even all the meta-analysis</p> <p>20 studies, on talc and ovarian cancer?</p> <p>21 A That is correct.</p> <p>22 Q And that's because either you weren't aware of</p> <p>23 them or you read them and didn't find them compelling</p> <p>24 or the attorneys didn't put it on the list for you to</p> <p>25 review; right?</p>

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<p>1 MS. AHERN: Objection. Form.</p> <p>2 THE WITNESS: Yeah, could you please --</p> <p>3 MR. DEARING: Sure.</p> <p>4 THE WITNESS: -- rephrase your question.</p> <p>5 BY MR. DEARING:</p> <p>6 Q So there are quite a few epidemiology studies</p> <p>7 and meta-analyses on talc and ovarian cancer that are</p> <p>8 not on either of your reference lists.</p> <p>9 A That's correct.</p> <p>10 Q Ms. Ahern just said on the record that they</p> <p>11 provided you the reference list.</p> <p>12 MS. AHERN: Objection. Form. The supplemental</p> <p>13 reference list is the one that we put together.</p> <p>14 MR. DEARING: Okay.</p> <p>15 BY MR. DEARING:</p> <p>16 Q If there are epidemiology studies that are not</p> <p>17 on your original reference list -- let me ask you: Did</p> <p>18 you put together your original reference list?</p> <p>19 A Yes.</p> <p>20 Q Did the lawyers help you do that?</p> <p>21 A Not really. It was me.</p> <p>22 Q Okay. The original reference list has a</p> <p>23 handful of epidemiology studies that we started to go</p> <p>24 through.</p> <p>25 A Yes. We were only up to like page 2. There</p>	<p>1 Do you agree with that?</p> <p>2 MS. AHERN: Objection. Form.</p> <p>3 THE WITNESS: That is correct.</p> <p>4 BY MR. DEARING:</p> <p>5 Q Now, because you didn't prepare the second</p> <p>6 list, the lawyers did, and the fact that some of those</p> <p>7 large studies are not on this list, do you interpret</p> <p>8 that to mean they didn't provide those to you or didn't</p> <p>9 think you should look at those?</p> <p>10 MS. AHERN: Objection. Form.</p> <p>11 THE WITNESS: I don't know what the -- what the</p> <p>12 reason was why they weren't included on that list.</p> <p>13 BY MR. DEARING:</p> <p>14 Q Before we get too far into the pathology weeds</p> <p>15 today, I want to ask you just some basic questions to</p> <p>16 make sure we're communicating well, like some</p> <p>17 definitions.</p> <p>18 For example, if I use the term "biologic</p> <p>19 plausibility," can you tell me what that means to you?</p> <p>20 Or does it mean anything to you?</p> <p>21 A It means something to me. I think it's a</p> <p>22 factor that would be very important in establishing</p> <p>23 causation. So the way I interpret -- view it is that</p> <p>24 it's -- biologic explanations often, really, base</p> <p>25 cellular studies or extracellular studies that could be</p>
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<p>1 may have been more.</p> <p>2 Q Right. But it's your list?</p> <p>3 A Yes.</p> <p>4 Q You wrote it. You made it.</p> <p>5 A Yes.</p> <p>6 Q You know there are quite a few epi studies</p> <p>7 that are not on that list; right?</p> <p>8 MS. AHERN: Objection. Form.</p> <p>9 THE WITNESS: That is correct.</p> <p>10 BY MR. DEARING:</p> <p>11 Q And there are quite a few that aren't on the</p> <p>12 list you made, and there are quite a few that still</p> <p>13 aren't on the list that the lawyer made, the</p> <p>14 supplemental list; right?</p> <p>15 A Please rephrase your question.</p> <p>16 Q Sure.</p> <p>17 Whatever reason, your reference list does not</p> <p>18 include quite a few epidemiology studies; right?</p> <p>19 MS. AHERN: Objection. Form.</p> <p>20 BY MR. DEARING:</p> <p>21 Q We've already established that.</p> <p>22 A We said that, right.</p> <p>23 Q The second list that I got yesterday also</p> <p>24 excludes quite a few epidemiology studies, including</p> <p>25 several meta-analysis studies.</p>	<p>1 incorporated with the human population studies to seem</p> <p>2 to go together in supporting a particular argument.</p> <p>3 Q Are you familiar with the nine Bradford Hill</p> <p>4 considerations that are used to assess the strength of</p> <p>5 proposed causal associations?</p> <p>6 MS. AHERN: Objection to form.</p> <p>7 THE WITNESS: I'm familiar with the Bradford Hill</p> <p>8 criteria, yes.</p> <p>9 BY MR. DEARING:</p> <p>10 Q Are you familiar with the biologic</p> <p>11 plausibility consideration of the Bradford Hill</p> <p>12 assessment?</p> <p>13 A That's what I just explained, I thought.</p> <p>14 Q Okay. That's what I'm asking you. I wanted</p> <p>15 to know is that your interpretation of the Bradford</p> <p>16 Hill criteria or assessment, or is that your,</p> <p>17 Dr. Kurman's, definition of biologic plausibility?</p> <p>18 MS. AHERN: Objection. Form.</p> <p>19 THE WITNESS: That's my interpretation, which is</p> <p>20 what I believe is the criterion spelled out by Bradford</p> <p>21 Hill.</p> <p>22 BY MR. DEARING:</p> <p>23 Q In the term "biologic plausibility," as you've</p> <p>24 just described it, how do you define "plausibility"?</p> <p>25 A I thought I just described it.</p>



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<p style="text-align: right;">Page 46</p> <p>1 Q Well, tell me what you mean by plausibility.</p> <p>2 MS. AHERN: Objection. Form. Asked and answered.</p> <p>3 THE WITNESS: I -- that's -- "plausibility" is a</p> <p>4 very general term. Bradford Hill describes not</p> <p>5 plausibility but biological plausibility, and that's</p> <p>6 what I just said a minute ago is my definition, which I</p> <p>7 thought was an interpretation of the way Bradford Hill</p> <p>8 used it.</p> <p>9 BY MR. DEARING:</p> <p>10 Q To you, is there a difference between biologic</p> <p>11 plausibility and biologic probability?</p> <p>12 MS. AHERN: Objection. Form.</p> <p>13 THE WITNESS: I don't know exactly what biologic</p> <p>14 probability is. I would stick with biologic</p> <p>15 plausibility.</p> <p>16 BY MR. DEARING:</p> <p>17 Q Does biologic plausibility have any</p> <p>18 application to pathology?</p> <p>19 A I think pathology studies could be used for</p> <p>20 evidence of biologic plausibility in the application of</p> <p>21 the Bradford Hill points.</p> <p>22 Q Right. Bradford Hill is an epidemiology</p> <p>23 causation assessment tool; right?</p> <p>24 A Correct.</p> <p>25 Q Right. And you've already said you're not</p>	<p style="text-align: right;">Page 48</p> <p>1 does the word "plausible" mean to you?</p> <p>2 MS. AHERN: Objection. Form.</p> <p>3 THE WITNESS: We never use the term "plausible" --</p> <p>4 BY MR. DEARING:</p> <p>5 Q Okay.</p> <p>6 A -- in -- in pathology.</p> <p>7 Q Okay.</p> <p>8 A I've never --</p> <p>9 Q So anytime that word "plausible" or</p> <p>10 "plausibility" comes up today, you're going to be</p> <p>11 discussing it in terms of epidemiological definitions,</p> <p>12 or are you going to use it some other way?</p> <p>13 MS. AHERN: Objection. Form.</p> <p>14 He's giving you his definition, which is not</p> <p>15 an epidemiologic deposition per se.</p> <p>16 MR. DEARING: I object. That's not true. For one,</p> <p>17 he keeps referring back to what is in the Bradford Hill</p> <p>18 criteria. I don't know what his definition is.</p> <p>19 MS. AHERN: You keep defining Bradford Hill</p> <p>20 criteria as epidemiology. It's not. I think that's</p> <p>21 the confusion here.</p> <p>22 MR. DEARING: Let's ask. Let me ask him. Okay. I</p> <p>23 don't need your commentary, but thank you.</p> <p>24 BY MR. DEARING:</p> <p>25 Q I believe you just testified that the</p>
<p style="text-align: right;">Page 47</p> <p>1 here to talk about epidemiology specifically; right?</p> <p>2 MS. AHERN: Objection. Form.</p> <p>3 THE WITNESS: I -- that's what I said.</p> <p>4 BY MR. DEARING:</p> <p>5 Q Okay. So I'm trying to determine whether the</p> <p>6 term "biologic plausibility" has any application to you</p> <p>7 outside the field of epidemiology.</p> <p>8 MS. AHERN: Objection. Form. Asked and answered.</p> <p>9 THE WITNESS: As I mentioned, this litigation is</p> <p>10 about causation, does talc cause ovarian cancer.</p> <p>11 And what virtually everyone agrees is, in</p> <p>12 order to come to a conclusion that it does, is to apply</p> <p>13 the Bradford Hill criteria, of which biologic</p> <p>14 plausibility is one among several that could go along</p> <p>15 to support causation.</p> <p>16 So in that regard, that's the way I'm</p> <p>17 interpreting and using "biologic plausibility."</p> <p>18 BY MR. DEARING:</p> <p>19 Q Do you agree that, in order to establish</p> <p>20 causation, you do not have to satisfy all nine of the</p> <p>21 Bradford Hill considerations?</p> <p>22 A I think that's correct, yes.</p> <p>23 Q I want you for this question, if you would, to</p> <p>24 step out of the world of epidemiology and Bradford Hill</p> <p>25 and just tell me, from a pathologist standpoint, what</p>	<p style="text-align: right;">Page 49</p> <p>1 definition you were giving of "biologic plausibility"</p> <p>2 was what's offered in the Bradford Hill assessment; is</p> <p>3 that right?</p> <p>4 A That's correct.</p> <p>5 Q Okay. Is that also your definition?</p> <p>6 A That's what I said.</p> <p>7 Q Okay. And you don't have any other definition</p> <p>8 of "plausibility" other than the way it is interpreted</p> <p>9 and defined as part of the Bradford Hill assessment?</p> <p>10 MS. AHERN: Objection. Form.</p> <p>11 THE WITNESS: Well, as I said, and I'll repeat it,</p> <p>12 that -- in this litigation, we're attempting to</p> <p>13 determine whether talc causes ovarian cancer. The --</p> <p>14 everyone seems to agree that the Bradford Hill criteria</p> <p>15 is the way to establish that. One of those criteria is</p> <p>16 biologic plausibility.</p> <p>17 My definition of "biologic plausibility" is</p> <p>18 the biologic plausibility that Bradford Hill uses in</p> <p>19 his several points.</p> <p>20 BY MR. DEARING:</p> <p>21 Q And you've articulated that to the best of</p> <p>22 your ability already?</p> <p>23 A Yes.</p> <p>24 Q As part of your methodology that you employed</p> <p>25 in arriving at your expert opinions regarding talcum</p>

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<p style="text-align: right;">Page 50</p> <p>1 powder and ovarian cancer, did you assess whether it is</p> <p>2 biologically plausible for talcum powder to cause</p> <p>3 inflammation?</p> <p>4 A Talcum powder can cause inflammation.</p> <p>5 Q Did you consider biologic plausibility that</p> <p>6 talcum powder could cause inflammation that might be a</p> <p>7 precursor to cancer?</p> <p>8 A For starters, I think it's very important to</p> <p>9 look at chronic inflammation. I've noticed that people</p> <p>10 tend to throw that around. "Chronic inflammation" is a</p> <p>11 very broad term.</p> <p>12 In terms of the talc exposure, it really</p> <p>13 refers to a very specific subtype of chronic</p> <p>14 inflammation -- I alluded to it earlier -- namely</p> <p>15 foreign-body giant cell granulomatous inflammation.</p> <p>16 And that, in my opinion, has not been shown to be</p> <p>17 associated with ovarian cancer.</p> <p>18 Q So are you saying the only type of chronic</p> <p>19 inflammation that might contribute to causing ovarian</p> <p>20 cancer is the giant cell granuloma-type inflammation?</p> <p>21 A No, no.</p> <p>22 MS. AHERN: Objection to form.</p> <p>23 THE WITNESS: That's not what I said.</p> <p>24 BY MR. DEARING:</p> <p>25 Q Okay. Can you repeat what you just --</p>	<p style="text-align: right;">Page 52</p> <p>1 that I ran across that a woman used a -- an</p> <p>2 antiperspirant that contained talc, and she got a</p> <p>3 skin -- a granuloma in her axilla. That would be about</p> <p>4 it.</p> <p>5 Q Giant cell granulomatous inflammation is</p> <p>6 hardly -- is virtually never seen in gynecologic</p> <p>7 tissue; right?</p> <p>8 A Very, very rare is it -- is it seen, that's</p> <p>9 correct.</p> <p>10 Q Is it your testimony that the giant cell</p> <p>11 granulomatous inflammation is the only kind of</p> <p>12 inflammation that might be a precursor for cancer?</p> <p>13 MS. AHERN: Objection. Form. Misstates his</p> <p>14 testimony.</p> <p>15 THE WITNESS: I didn't say that at all.</p> <p>16 BY MR. DEARING:</p> <p>17 Q Okay. What other type of chronic inflammation</p> <p>18 might be a precursor for cancer?</p> <p>19 MS. AHERN: Objection. Form.</p> <p>20 THE WITNESS: In my opinion, inflammation very</p> <p>21 rarely initiates cancer. It can be seen certainly in</p> <p>22 association with cancer, but it's usually -- it</p> <p>23 typically occurs later in the whole process of</p> <p>24 malignancy.</p> <p>25 ///</p>
<p style="text-align: right;">Page 51</p> <p>1 A Sure.</p> <p>2 Q -- tried to explain.</p> <p>3 A I said that chronic inflammation is a very</p> <p>4 broad term. And in the context of this litigation,</p> <p>5 specifically does talc cause ovarian cancer, talc</p> <p>6 causes a very specific -- or I should say induces a</p> <p>7 very specific type of inflammation, which is referred</p> <p>8 to as foreign-body giant cell granulomatous</p> <p>9 inflammation. And that type of inflammation is not</p> <p>10 associated with ovarian cancer.</p> <p>11 Q How do you know that talc used in body powders</p> <p>12 elicits that kind of inflammation that you just</p> <p>13 described, giant cell granuloma inflammation?</p> <p>14 A Well, talc is what's -- what I'm referring to.</p> <p>15 In the literature, talc has been used in a variety of</p> <p>16 situations where it's caused foreign-body giant cell</p> <p>17 granulomatous inflammation.</p> <p>18 Q What are some examples of those situations</p> <p>19 where talc caused that?</p> <p>20 A Pleurodesis.</p> <p>21 Q Okay.</p> <p>22 A Contamination from gloves.</p> <p>23 Q Right.</p> <p>24 A That would be the -- well, sometimes it's been</p> <p>25 seen in creating skin granulomas. I remember one case</p>	<p style="text-align: right;">Page 53</p> <p>1 BY MR. DEARING:</p> <p>2 Q And in that statement, when you use the term</p> <p>3 "inflammation," are you talking giant cell</p> <p>4 granulomatous inflammation, chronic inflammation, or</p> <p>5 something else?</p> <p>6 A I'm --</p> <p>7 MS. AHERN: Objection. Form.</p> <p>8 THE WITNESS: I'm not talking about foreign-body</p> <p>9 giant cell granulomatous inflammation, which, as I said</p> <p>10 earlier, I don't see any evidence of causing ovarian</p> <p>11 cancer.</p> <p>12 So when I was referring in a more general</p> <p>13 statement to respond to your question about chronic</p> <p>14 inflammation, I was referring to chronic inflammation</p> <p>15 of a different type.</p> <p>16 BY MR. DEARING:</p> <p>17 Q Okay. You first said when we started talking</p> <p>18 about inflammation, that it's very important to make</p> <p>19 sure we're talking about the same kind of inflammation,</p> <p>20 because they are different types; right?</p> <p>21 A That's correct.</p> <p>22 Q That's why I'm trying to be very specific</p> <p>23 about this.</p> <p>24 Are you aware of any other types of chronic</p> <p>25 inflammation, other than giant cell or granulomatous</p>

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<p style="text-align: right;">Page 54</p> <p>1 inflammation, that can cause cancer?</p> <p>2 MS. AHERN: Objection. Form.</p> <p>3 THE WITNESS: We're really talking about, again, my</p> <p>4 testimony specifically concerned with ovarian cancer.</p> <p>5 So I'm not talking about pancreatic cancer, lung</p> <p>6 cancer, stomach cancer.</p> <p>7 I mean, cancers are all different, and I'm not</p> <p>8 going to stand up and tell you -- respond to that</p> <p>9 question because it's a very general question.</p> <p>10 BY MR. DEARING:</p> <p>11 Q I thought it was a very specific question.</p> <p>12 There -- you discuss in your report</p> <p>13 essentially two types of inflammation -- chronic</p> <p>14 inflammation, infectious chronic inflammation and</p> <p>15 noninfectious; right?</p> <p>16 MS. AHERN: Objection. Form.</p> <p>17 THE WITNESS: That's one type.</p> <p>18 BY MR. DEARING:</p> <p>19 Q That's two types.</p> <p>20 A Well, two types.</p> <p>21 Q Okay. Are there any other types of chronic</p> <p>22 inflammation?</p> <p>23 A Just general chronic inflammation not</p> <p>24 associated -- well, infectious or noninfectious, right.</p> <p>25 Q Okay. So breaking inflammation down, there's</p>	<p style="text-align: right;">Page 56</p> <p>1 MS. AHERN: Objection. Form.</p> <p>2 THE WITNESS: I haven't read the other experts, as</p> <p>3 you yourself pointed out. I've read Dr. Kane's</p> <p>4 explanation. And, as I said, her explanation, I</p> <p>5 believe, is invalid and unreliable.</p> <p>6 BY MR. DEARING:</p> <p>7 Q So as you sit here today, you have no idea how</p> <p>8 the plaintiffs, through their experts, are alleging</p> <p>9 talc causes ovarian cancer?</p> <p>10 A I didn't --</p> <p>11 MS. AHERN: Objection. Form.</p> <p>12 THE WITNESS: Excuse me. I've interrupted you.</p> <p>13 I didn't read those expert reports. I don't</p> <p>14 know what they said.</p> <p>15 BY MR. DEARING:</p> <p>16 Q I know you haven't read the reports, but are</p> <p>17 you saying that you don't know what the plaintiffs'</p> <p>18 experts are alleging as a mechanistic process of how</p> <p>19 talc causes ovarian cancer?</p> <p>20 MS. AHERN: Objection. Form.</p> <p>21 THE WITNESS: How would I know if I can't read the</p> <p>22 reports? I don't know what they said.</p> <p>23 BY MR. DEARING:</p> <p>24 Q What's your understanding of Dr. Kane's</p> <p>25 opinion on how talc causes ovarian cancer?</p>
<p style="text-align: right;">Page 55</p> <p>1 two broad types, either infectious or noninfectious;</p> <p>2 right?</p> <p>3 MS. AHERN: Objection.</p> <p>4 Are you talking about foreign body, or are you</p> <p>5 talking about general inflammation?</p> <p>6 THE WITNESS: Right. Foreign-body giant cell</p> <p>7 reaction is a type of -- type of inflammation that can</p> <p>8 be either infectious or noninfectious. But it's</p> <p>9 different than other types of chronic inflammation,</p> <p>10 which may be infectious or noninfectious.</p> <p>11 BY MR. DEARING:</p> <p>12 Q What's your understanding of the plaintiffs'</p> <p>13 experts' explanation for how talc causes chronic</p> <p>14 inflammation which can cause ovarian cancer?</p> <p>15 A You're specifically referring to Dr. Kane?</p> <p>16 Q Well, it's not just Dr. Kane's position, is --</p> <p>17 well, you probably haven't read all the other</p> <p>18 plaintiffs' positions.</p> <p>19 So as you understand it, based on whatever</p> <p>20 you've looked at, what's your understanding of that</p> <p>21 mechanistic process?</p> <p>22 A I believe it's unreliable and invalid.</p> <p>23 Q No, I don't want your commentary. I want what</p> <p>24 do you understand that the plaintiffs' experts are</p> <p>25 alleging.</p>	<p style="text-align: right;">Page 57</p> <p>1 A I just told you. I said I thought it's</p> <p>2 invalid and unreliable.</p> <p>3 Q I'm not asking you for what you think of it.</p> <p>4 I'm asking you what's your understanding of what she is</p> <p>5 saying.</p> <p>6 How does she describe the mechanism of how</p> <p>7 talc causes ovarian cancer?</p> <p>8 A Well, why don't we go through her report, and</p> <p>9 I can discuss those with you.</p> <p>10 Q You don't remember?</p> <p>11 A I want to go through them so we get them</p> <p>12 absolutely right.</p> <p>13 Q I'll come back to it --</p> <p>14 A Okay.</p> <p>15 Q -- because that's a big part of this.</p> <p>16 A Okay.</p> <p>17 Q I just wanted to know what you remembered.</p> <p>18 A Okay.</p> <p>19 Q Is it your opinion that the notion that talc</p> <p>20 can cause chronic inflammation, which can cause ovarian</p> <p>21 cancer, is that process biologically plausible to you?</p> <p>22 A No.</p> <p>23 Q Not the slightest bit?</p> <p>24 A No.</p> <p>25 Q Why do you say that?</p>

15 (Pages 54 to 57)

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<p style="text-align: right;">Page 58</p> <p>1 A Because, as I -- based on my experience and my 2 reviewing of the literatures up to this point, talc 3 induces a specific type of chronic inflammation that 4 we're terming foreign-body granulomatous inflammation. 5 I have never seen that, in all my experience 6 in ovarian cancer, foreign-body giant cell reaction. 7 So, I mean, I've seen chronic inflammation in ovarian 8 cancer. No one would dispute that. But specifically 9 the kind of granuloma -- the kind of inflammation 10 induced by talc, I have not observed. 11 Q Do you know whether you've treated patients or 12 performed surgical pathology on patient specimens of 13 women who used talcum powder for feminine hygiene 14 long-term? 15 A I wouldn't know if they haven't used it, but I 16 haven't seen any evidence of it when I looked at tissue 17 specimens. 18 Q So if you're looking at -- 19 MS. AHERN: David, when you get to a stopping 20 point, can we take a potty break. 21 MR. DEARING: Sure. Let me just wrap up this. 22 MS. AHERN: Sure. 23 BY MR. DEARING: 24 Q So what you're saying is you don't believe 25 that it's biologically plausible that talc can cause</p>	<p style="text-align: right;">Page 60</p> <p>1 carcinomas, due to extrusion of keratin, which can 2 produce a foreign-body giant cell reaction. That, I've 3 seen. 4 I've seen teratomas, nothing to do with the 5 litigation we're talking about now. It's a completely 6 different kind of tumor. It's a germ cell tumor. And 7 I've seen, with extrusion of keratin in those 8 instances, a foreign-body giant cell reaction. 9 Apart from those instances and maybe suture 10 granulomas, which, again, are pretty obvious, I haven't 11 seen that type of reaction in association with ovarian 12 cancer during my entire career. 13 BY MR. DEARING: 14 Q And are you saying you haven't seen that type 15 of inflammatory reaction in gynecologic tissue to any 16 foreign particle? 17 A Well -- 18 MS. AHERN: Objection. Form. 19 THE WITNESS: -- as I just said -- 20 BY MR. DEARING: 21 Q Except for sutures? 22 A Suture granulomas and the keratin that I 23 mentioned, which is -- 24 Q That's endogenous? 25 A Yeah, but it -- yeah, okay. Aside from that,</p>
<p style="text-align: right;">Page 59</p> <p>1 chronic inflammation that can cause ovarian cancer 2 because you've never seen it; right? 3 MS. AHERN: Objection. Form. 4 THE WITNESS: We need to specifically say again the 5 kind of inflammation I'm talking about is foreign-body 6 giant cell inflammation, which is the type of 7 inflammation that's implicated with talc exposure. 8 Talc doesn't produce other types of chronic 9 inflammation. 10 BY MR. DEARING: 11 Q Again, you said you've never seen, in your 12 career, a chronic inflammatory response to talc like 13 giant cell granulomas in gynecologic tissue; is that 14 what you are saying? 15 A That's correct. 16 Q So my question is, you're saying it's not 17 biologically plausible because you've never seen it; 18 right? 19 MS. AHERN: Objection. Form. 20 THE WITNESS: Is that your question? 21 I've spent, as I said, 40 years looking at 22 gynecologic pathology specimens, including a large 23 number of ovarian cancers, and I have never seen a 24 foreign body -- I've seen a foreign-body giant cell 25 reaction in rare ovarian tumors, endometrial</p>	<p style="text-align: right;">Page 61</p> <p>1 I can't recall seeing anything, no. 2 Q So aside from surgical sutures -- 3 A Uh-huh. 4 Q -- you've never seen a giant cell 5 granulomatous foreign-body reaction in gynecologic 6 tissue? 7 A Again, I mentioned the keratin -- 8 Q I'm sorry. Responding to foreign material? 9 MS. AHERN: Objection. Form. 10 THE WITNESS: That's correct. 11 MR. DEARING: Want to take a break? 12 MS. AHERN: Thank you. 13 VIDEO OPERATOR BROWN: The time is now 10:31. 14 Going off the record. 15 (Recess taken.) 16 VIDEO OPERATOR BROWN: Time is now 10:53. Back on 17 the record. 18 BY MR. DEARING: 19 Q Right before the break, Doctor, you made a 20 statement to the effect of "Talc doesn't produce other 21 types of chronic inflammation that can cause cancer." 22 Did you say something like that? 23 A That's -- that's what I said. 24 Q So what other types of inflammation do cause 25 cancer that you're referring to?</p>

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<p style="text-align: right;">Page 62</p> <p>1 A Well, again, in the ovary, there's absolutely</p> <p>2 no evidence that inflammation causes cancer. I want to</p> <p>3 be clear about that. Now, there may be other tumors</p> <p>4 where it plays a role, but those are not things that</p> <p>5 I'm familiar with.</p> <p>6 Q So are you saying that it's not biologically</p> <p>7 plausible that other types of inflammation can cause</p> <p>8 ovarian cancer?</p> <p>9 MS. AHERN: Objection. Form.</p> <p>10 THE WITNESS: I said I haven't observed it and I</p> <p>11 wasn't aware of anything in the literature that showed</p> <p>12 chronic inflammation causing ovarian cancer.</p> <p>13 BY MR. DEARING:</p> <p>14 Q So because you haven't observed it, is it your</p> <p>15 opinion that it's not biologically plausible?</p> <p>16 MS. AHERN: Objection. Form. Misstates his</p> <p>17 testimony.</p> <p>18 THE WITNESS: Well, as I said, I haven't seen it</p> <p>19 nor have I read any paper that has indicated that it</p> <p>20 was a causative factor of ovarian cancer.</p> <p>21 BY MR. DEARING:</p> <p>22 Q And the question is, is it biologically</p> <p>23 plausible?</p> <p>24 MS. AHERN: Objection. Form.</p> <p>25 THE WITNESS: Insofar as what the literature has</p>	<p style="text-align: right;">Page 64</p> <p>1 Q And when I -- so my question is, the talc that</p> <p>2 you're referring to that elicits that type of response</p> <p>3 is talc left behind from either a surgical tool or a</p> <p>4 surgical glove or something like that; right?</p> <p>5 MS. AHERN: Objection. Form.</p> <p>6 THE WITNESS: That's correct.</p> <p>7 BY MR. DEARING:</p> <p>8 Q And do you agree that the talc used</p> <p>9 industrially for surgical gloves back in the '70s and</p> <p>10 before, and potentially contaminating a surgical tool,</p> <p>11 is different than cosmetic talc in baby powder?</p> <p>12 MS. AHERN: Objection. Form.</p> <p>13 THE WITNESS: I'm not exactly sure of that. This</p> <p>14 is something that I don't have expertise in. I would</p> <p>15 defer to a mineralogist to describe the references</p> <p>16 between what you describe as industrial and cosmetic</p> <p>17 talc.</p> <p>18 BY MR. DEARING:</p> <p>19 Q Just to close the circle, is it your opinion</p> <p>20 that it's not biologically plausible that any type of</p> <p>21 chronic inflammation can cause ovarian cancer?</p> <p>22 A As I said, I've seen no evidence of chronic</p> <p>23 inflammation causing ovarian cancer.</p> <p>24 Q My question is, is it biologically plausible,</p> <p>25 in your opinion, that some type of inflammation can</p>
<p style="text-align: right;">Page 63</p> <p>1 described about the type of inflammation induced by</p> <p>2 talc, which has never shown any evidence of causing</p> <p>3 cancer, I would say it's not plausible.</p> <p>4 BY MR. DEARING:</p> <p>5 Q And the type of inflammation caused by talc</p> <p>6 that you're referring to is talc typically left inside</p> <p>7 the body from a contaminated surgical tool, for</p> <p>8 example, surgical gloves maybe back in the day when</p> <p>9 they still had talc; right?</p> <p>10 A Yeah.</p> <p>11 MS. AHERN: Objection. Form.</p> <p>12 BY MR. DEARING:</p> <p>13 Q So you're not suggesting that cosmetic-grade</p> <p>14 baby powder talc is the type of talc that you're</p> <p>15 referring to that you've seen these other inflammatory</p> <p>16 responses to; right?</p> <p>17 MS. AHERN: Objection. Form.</p> <p>18 THE WITNESS: Please repeat -- rephrase that</p> <p>19 question.</p> <p>20 MR. DEARING: Sure.</p> <p>21 BY MR. DEARING:</p> <p>22 Q You said you expect the inflammatory response</p> <p>23 to talc to be giant cell granulomatous foreign-body</p> <p>24 response; right?</p> <p>25 A Yes.</p>	<p style="text-align: right;">Page 65</p> <p>1 cause ovarian cancer?</p> <p>2 A Well, as I haven't seen it --</p> <p>3 MS. AHERN: Objection. Form.</p> <p>4 THE WITNESS: -- and I haven't read about it, I --</p> <p>5 and it's been studied, I would say it's not</p> <p>6 biologically plausible.</p> <p>7 BY MR. DEARING:</p> <p>8 Q What methodology do you use to reach</p> <p>9 conclusions about biologic plausibility?</p> <p>10 A Well, to begin with, as I said early on in the</p> <p>11 deposition, I have spent 40 years looking at</p> <p>12 gynecologic pathology, which ovarian cancer is one of</p> <p>13 those. I have read extensively and kept up with the</p> <p>14 literature. I've edited the third, fourth, fifth,</p> <p>15 sixth, and in the process of the seventh edition, of</p> <p>16 Blaustein's pathology textbook.</p> <p>17 I was the lead author on the 2014 WHO</p> <p>18 classification of ovarian cancer.</p> <p>19 I participate in meetings, both domestically</p> <p>20 and internationally. I review papers, as we discussed</p> <p>21 earlier.</p> <p>22 So I think all of that together amounts to the</p> <p>23 way I evaluate biological plausibility.</p> <p>24 Q Is that a complete description of your</p> <p>25 methodology used to evaluate biologic plausibility?</p>



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<p style="text-align: right;">Page 66</p> <p>1 A Well, as I mentioned also, in this particular</p> <p>2 case, I reviewed what Dr. Kane claimed or alleged that</p> <p>3 were causative agents. I review those papers</p> <p>4 specifically. So that in addition to everything else I</p> <p>5 described.</p> <p>6 Q So your methodology for evaluating biologic</p> <p>7 plausibility is your reliance on your experience, your</p> <p>8 review of the literature, your publication literature,</p> <p>9 I guess, and your review of other expert opinions on</p> <p>10 it?</p> <p>11 MS. AHERN: Objection. Form.</p> <p>12 BY MR. DEARING:</p> <p>13 Q Did I leave anything out?</p> <p>14 A I think that pretty much covers it.</p> <p>15 Q And, of course, you haven't published on talc</p> <p>16 and ovarian cancer?</p> <p>17 A That's correct.</p> <p>18 Q And you think that's a complete, sound,</p> <p>19 reliable methodology for assessing plausible --</p> <p>20 biologic plausibility?</p> <p>21 A Please repeat the question.</p> <p>22 Q Sure.</p> <p>23 Do you think that that is a complete and</p> <p>24 reliable methodology for assessing plausible --</p> <p>25 biologic plausibility?</p>	<p style="text-align: right;">Page 68</p> <p>1 have.</p> <p>2 BY MR. DEARING:</p> <p>3 Q Okay. Do you agree that inert particles can</p> <p>4 cause an inflammatory response that could trigger or be</p> <p>5 a precursor to cancer?</p> <p>6 MS. AHERN: Objection. Form.</p> <p>7 THE WITNESS: As I just said, again, I think we</p> <p>8 specifically -- in this litigation referring to talc as</p> <p>9 an inert substance that does not produce an</p> <p>10 inflammatory reaction that can cause ovarian cancer.</p> <p>11 BY MR. DEARING:</p> <p>12 Q I understand that about talc and that's your</p> <p>13 opinion.</p> <p>14 My question is just because a foreign particle</p> <p>15 is inert doesn't mean that it can't cause a</p> <p>16 foreign-body inflammatory reaction that could be a</p> <p>17 precursor lesion to cancer; right?</p> <p>18 MS. AHERN: Objection. Form.</p> <p>19 THE WITNESS: No, I disagree with that.</p> <p>20 BY MR. DEARING:</p> <p>21 Q Well, you would agree that talc does elicit an</p> <p>22 inflammatory response in tissue; right?</p> <p>23 A A specific type of inflammatory reaction, we</p> <p>24 described foreign-body giant cell granulomatous</p> <p>25 reaction, yes.</p>
<p style="text-align: right;">Page 67</p> <p>1 A I believe it is, yes.</p> <p>2 Q On page 13 of your report -- and I don't know</p> <p>3 if you need to look this up. You use the word "inert."</p> <p>4 You suggest that talc is inert.</p> <p>5 I just want to know, what does "inert" mean to</p> <p>6 you?</p> <p>7 A Well, I relied upon -- and I think IARC used</p> <p>8 that exact same terminology, in fact. And I think in</p> <p>9 contrast to an inflammatory agent, for example, which</p> <p>10 elicits more of a systemic immune response, talc is</p> <p>11 very localized and it induces the migration of</p> <p>12 macrophages, which then become histiocytes in tissue</p> <p>13 which surround it and engulf it but don't elicit an</p> <p>14 immune kind of response. So, in that respect, I think</p> <p>15 it is, quote/unquote, inert.</p> <p>16 Q What do you mean by "immune kind of response"?</p> <p>17 A Well, where -- antigen-presenting cells,</p> <p>18 lymphocytes. Lymphocytes induce various types of</p> <p>19 reactions in response to an infectious agent, for</p> <p>20 example. That's not -- that doesn't occur with talc.</p> <p>21 Q So you told me why you think talc is inert,</p> <p>22 but what does it mean to be inert? How do you define</p> <p>23 "inert," just the word?</p> <p>24 MS. AHERN: Objection. Form.</p> <p>25 THE WITNESS: Well, I can't do any better than I</p>	<p style="text-align: right;">Page 69</p> <p>1 Q And so if a large talc particle in the</p> <p>2 peritoneal cavity elicits an inflammatory giant cell</p> <p>3 granulomatous response and that inflammation is</p> <p>4 chronic, can't that chronic inflammatory response</p> <p>5 evolve into a lesion or a precursor lesion for cancer?</p> <p>6 MS. AHERN: Objection. Form. Assumes facts.</p> <p>7 THE WITNESS: Could you break that? It was a</p> <p>8 complex question.</p> <p>9 BY MR. DEARING:</p> <p>10 Q It was a slow question, but it's a simple</p> <p>11 question.</p> <p>12 A Okay.</p> <p>13 Q If a large talc particle is left in the</p> <p>14 peritoneal cavity and evokes the type of response that</p> <p>15 you say it should, a inflammatory giant cell</p> <p>16 granulomatous foreign-body response, and it becomes a</p> <p>17 chronic condition, can't that be a precursor lesion to</p> <p>18 cancer, some kind of peritoneal cancer?</p> <p>19 MS. AHERN: Objection.</p> <p>20 THE WITNESS: I don't believe that's true. It's</p> <p>21 been demonstrated, as you've alluded to before,</p> <p>22 surgical gloves can introduce talc into the peritoneal</p> <p>23 cavity. And I'm not aware of any cancer that's been</p> <p>24 associated or induced by that contamination of talc in</p> <p>25 the peritoneal cavity.</p>

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<p style="text-align: right;">Page 70</p> <p>1 BY MR. DEARING:</p> <p>2 Q Do you agree with me that inert particles can</p> <p>3 evoke a chronic inflammatory response, foreign-body</p> <p>4 response, in the body?</p> <p>5 A As I said, inert particles induce a</p> <p>6 foreign-body giant cell reaction of the sort -- similar</p> <p>7 to what talc does.</p> <p>8 Q Do you agree that talc causes inflammation in</p> <p>9 epithelial ovarian cells?</p> <p>10 A No.</p> <p>11 MS. AHERN: Objection. Form.</p> <p>12 THE WITNESS: I don't.</p> <p>13 BY MR. DEARING:</p> <p>14 Q Do you believe that talc can cause</p> <p>15 inflammation in any kind of ovarian cells?</p> <p>16 A Talc produce -- what kind of ovarian cell are</p> <p>17 we talking about, for starters?</p> <p>18 Q Well, any kind you want to identify. Any</p> <p>19 kind -- let me ask it again.</p> <p>20 Do you have any opinions about whether</p> <p>21 exposure to talc could cause any type of reaction in</p> <p>22 any type of ovarian cells?</p> <p>23 A I've never seen any evidence of that or read</p> <p>24 any evidence of that.</p> <p>25 Q Does that mean you don't think that's</p>	<p style="text-align: right;">Page 72</p> <p>1 So the fact that it might show some reaction</p> <p>2 in epithelial cells of the ovary, which some biologic</p> <p>3 studies -- in vitro studies have shown, doesn't have</p> <p>4 anything to do with causation of ovarian cancer.</p> <p>5 BY MR. DEARING:</p> <p>6 Q I realize that's your opinion and you've</p> <p>7 published that, even. But you agree with me that not</p> <p>8 all gynecologic pathologists agree with you that</p> <p>9 invasive ovarian carcinomas start in the fallopian</p> <p>10 tube?</p> <p>11 MS. AHERN: Objection. Form.</p> <p>12 THE WITNESS: Could you define which kind of</p> <p>13 carcinomas you're talking about?</p> <p>14 BY MR. DEARING:</p> <p>15 Q Sure. Let's start with serous invasive</p> <p>16 carcinomas. You believe that's those typically start</p> <p>17 in the fallopian tubes; right?</p> <p>18 A Low-grade or high-grade?</p> <p>19 Q High-grade.</p> <p>20 A High-grade, I believe, start in the fallopian</p> <p>21 tube.</p> <p>22 Q And you would agree with not all gynecologic</p> <p>23 pathologists degree with you on that; right?</p> <p>24 A The consensus at this point in time, 2019, is</p> <p>25 that a vast, vast majority of pathologists believe that</p>
<p style="text-align: right;">Page 71</p> <p>1 biologically plausible because you have never seen it?</p> <p>2 MS. AHERN: Objection. Form.</p> <p>3 THE WITNESS: Let me -- when you're talking</p> <p>4 about -- you know, the ovary is a complex organ.</p> <p>5 Contains germ cells, contains stromal cells, contains</p> <p>6 surface epithelial cells.</p> <p>7 Which cells are you actually talking about?</p> <p>8 BY MR. DEARING:</p> <p>9 Q I'm talking about any type of ovarian cell.</p> <p>10 I'm leaving it up to you to use any cell you like. Are</p> <p>11 you telling me that talc causes no reaction in any type</p> <p>12 of ovarian cell that you know of?</p> <p>13 A Well, there have been in vitro studies which</p> <p>14 have used ovarian cells and shown some reaction, if</p> <p>15 that's what you mean. I've seen that.</p> <p>16 Q Have you seen any studies that suggest that</p> <p>17 epithelial cells exposed to talc undergo neoplastic</p> <p>18 changes?</p> <p>19 MS. AHERN: Objection. Form.</p> <p>20 THE WITNESS: I think it is important to point out,</p> <p>21 before we get all hung up on ovarian epithelial cells,</p> <p>22 that if we are talking about -- which, basically, we're</p> <p>23 talking about causation -- is that ovarian cancer does</p> <p>24 not start from ovarian epithelial cells; it starts from</p> <p>25 fallopian tube cells.</p>	<p style="text-align: right;">Page 73</p> <p>1 ovarian -- high-grade serous carcinoma begins in</p> <p>2 fallopian tube epithelium.</p> <p>3 Q Vast, vast majority of them believe that? Is</p> <p>4 that what you are saying?</p> <p>5 A Well, including your plaintiffs' expert, Susan</p> <p>6 Kane -- Sarah Kane.</p> <p>7 Q I understand.</p> <p>8 We'll come back to that.</p> <p>9 Is it your testimony that it's not</p> <p>10 biologically plausible that talc could cause any type</p> <p>11 of inflammatory reaction in any type of ovarian cell?</p> <p>12 MS. AHERN: Objection. Form.</p> <p>13 THE WITNESS: Well, as I've said, there are some</p> <p>14 in vitro studies in which exposure to talc has resulted</p> <p>15 in some proliferation and -- excuse me. I take that</p> <p>16 back, proliferation -- expression of some markers that</p> <p>17 are markers of inflammation. Those studies I won't get</p> <p>18 into it because I'm not, as I said, a bench scientist.</p> <p>19 BY MR. DEARING:</p> <p>20 Q So there is some evidence that some ovarian</p> <p>21 cells will respond in an inflammatory way to talc</p> <p>22 exposure?</p> <p>23 MS. AHERN: Objection. Form.</p> <p>24 BY MR. DEARING:</p> <p>25 Q Is that what you are saying? There are</p>

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<p>1 studies.</p> <p>2 A That's what I said just now.</p> <p>3 Q Okay. Just making sure I understand.</p> <p>4 Do you agree that asbestos is a known human</p> <p>5 carcinogen?</p> <p>6 A Yes, I --</p> <p>7 MS. AHERN: Objection. Form.</p> <p>8 THE WITNESS: Yes, I agree that asbestos is a known</p> <p>9 carcinogen.</p> <p>10 BY MR. DEARING:</p> <p>11 Q And you're familiar with IARC, right, the</p> <p>12 International Agency for Research on Cancer?</p> <p>13 A I -- well, I am, yes.</p> <p>14 Q And it's an international intergovernmental</p> <p>15 agency created in 1965; right?</p> <p>16 MS. AHERN: Objection. Form.</p> <p>17 THE WITNESS: I don't know when it was created, but</p> <p>18 I'm familiar with IARC.</p> <p>19 BY MR. DEARING:</p> <p>20 Q And it forms part of the World Health</p> <p>21 Organization, which is part of the United Nations;</p> <p>22 right?</p> <p>23 A It's part of the World Health Organization.</p> <p>24 Q And there are 25 member nations, and it's made</p> <p>25 up of probably a thousand or more scientists.</p>	<p>1 second.</p> <p>2 I have -- no, I can't say that I have looked</p> <p>3 at their mission statement.</p> <p>4 Q Okay. Well, in the second paragraph, it says:</p> <p>5 "The objective of the IARC is to</p> <p>6 promote international collaboration in</p> <p>7 cancer research. The agency is</p> <p>8 interdisciplinary, bringing together</p> <p>9 skills in epidemiology, laboratory</p> <p>10 sciences, and biostatistics to identify</p> <p>11 the causes of cancer so that</p> <p>12 preventative -- preventive measures may</p> <p>13 be adopted and the burden of disease and</p> <p>14 associated suffering reduced. A</p> <p>15 significant feature of the IARC is its</p> <p>16 expertise in coordinating research</p> <p>17 across countries and organizations. Its</p> <p>18 independent role as an international</p> <p>19 organization facilitates this activity.</p> <p>20 The agency has a particular interest in</p> <p>21 conducting research in low- and</p> <p>22 middle-income countries through</p> <p>23 partnerships and collaborations with</p> <p>24 researchers in these regions."</p> <p>25 Is that your understanding of IARC's mission?</p>
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<p>1 Would you agree with that?</p> <p>2 A You'd have to show me the data for that. I</p> <p>3 don't know.</p> <p>4 Q Okay. Well, would you agree it's made up of</p> <p>5 at least hundreds of scientists?</p> <p>6 MS. AHERN: Objection. Form.</p> <p>7 THE WITNESS: I want to see what you're talking</p> <p>8 about. I don't know how many are involved.</p> <p>9 (The document referenced below was</p> <p>10 marked Deposition Exhibit 3 for</p> <p>11 identification and is appended hereto.)</p> <p>12 BY MR. DEARING:</p> <p>13 Q I'm handing you Exhibit 3, which is taken from</p> <p>14 the IARC website, and it identifies IARC's mission</p> <p>15 statement.</p> <p>16 Have you ever seen that before?</p> <p>17 MS. AHERN: Objection to the document. Does it</p> <p>18 have a date?</p> <p>19 MR. DEARING: Well, I printed it off yesterday, but</p> <p>20 no.</p> <p>21 MS. AHERN: Okay.</p> <p>22 BY MR. DEARING:</p> <p>23 Q Have you ever looked at IARC's mission</p> <p>24 statement before?</p> <p>25 A I can't -- hmm. I got twisted up here for a</p>	<p>1 A Well --</p> <p>2 MS. AHERN: Objection. Form.</p> <p>3 THE WITNESS: -- that's what it states.</p> <p>4 BY MR. DEARING:</p> <p>5 Q Do you have any --</p> <p>6 A I have no reason --</p> <p>7 Q -- that that's not --</p> <p>8 A -- to argue with it.</p> <p>9 Q Okay. Are you aware that in 2009 IARC issued</p> <p>10 a monograph that stated that there is sufficient</p> <p>11 evidence now available to show that asbestos causes</p> <p>12 cancer of the ovary?</p> <p>13 A I am aware of it. I would question their</p> <p>14 methodology and who the individuals were on that</p> <p>15 committee that came to that conclusion, because, in</p> <p>16 looking at that, and I am familiar with it, I had</p> <p>17 significant issues with the -- their methodology that</p> <p>18 they used and the conclusions that they drew from that.</p> <p>19 Q Do you believe asbestos can cause ovarian</p> <p>20 cancer?</p> <p>21 A At this point, I do not believe that's the</p> <p>22 case.</p> <p>23 Q That same monograph states that "Studies</p> <p>24 suggest that asbestos can accumulate in the ovaries of</p> <p>25 women who are exposed to it."</p>

20 (Pages 74 to 77)

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<p>1 Do you agree with that statement?</p> <p>2 MS. AHERN: Objection. Form.</p> <p>3 THE WITNESS: The -- as I recall, those studies</p> <p>4 that they're citing were inhalation studies of very --</p> <p>5 of occupational -- of people that were exposed</p> <p>6 occupationally or environmentally to very high doses of</p> <p>7 asbestos and which bear -- nothing to do with perineal</p> <p>8 exposure.</p> <p>9 BY MR. DEARING:</p> <p>10 Q The question is do you agree that studies</p> <p>11 suggest that asbestos can accumulate in the ovaries of</p> <p>12 women who are exposed to it?</p> <p>13 A I'd have to see the studies where it shows</p> <p>14 that.</p> <p>15 Q So you don't have an opinion on that?</p> <p>16 A No. I said I'd like to see the studies. I</p> <p>17 don't believe -- I'd like to see it.</p> <p>18 Q I don't have them.</p> <p>19 A Okay.</p> <p>20 Q So I'm asking do you have an opinion on that.</p> <p>21 A My opinion is, as I said earlier, asbestos</p> <p>22 does not cause ovarian cancer.</p> <p>23 (The document referenced below was</p> <p>24 marked Deposition Exhibit 4 for</p> <p>25 identification and is appended hereto.)</p>	<p>1 tumor site for chromium cancer; right?</p> <p>2 A Yes.</p> <p>3 Q And then right below that is nickel, nickel</p> <p>4 compounds, is identified as a Group 1 agent. And it</p> <p>5 identifies tumor sites for which there is sufficient</p> <p>6 evidence in humans as lungs, nasal cavity, and</p> <p>7 paranasal sinuses.</p> <p>8 Do you agree?</p> <p>9 A I see that.</p> <p>10 Q Do you agree that arsenic, chromium, and</p> <p>11 nickel are known human carcinogens?</p> <p>12 A Well, according to IARC, they are.</p> <p>13 Q Do you agree that they are?</p> <p>14 A I agree with IARC on that.</p> <p>15 Q And then right below that, another Group 1</p> <p>16 agent, it says asbestos. And then it identifies --</p> <p>17 one, two, three, four -- six types of asbestos. And it</p> <p>18 states the tumor sites for which there is sufficient</p> <p>19 evidence in humans are lung, mesothelioma, larynx, and</p> <p>20 ovary.</p> <p>21 And are you saying now that you disagree that</p> <p>22 the ovary -- that this is sufficient evidence that</p> <p>23 asbestos can cause cancer in the ovaries?</p> <p>24 A I agree that the -- I agree with what I said</p> <p>25 earlier, that the evidence upon which IARC came to the</p>
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<p>1 BY MR. DEARING:</p> <p>2 Q This is Exhibit 4, and this is the monograph</p> <p>3 I'm referring to.</p> <p>4 If you look at -- have you seen this before,</p> <p>5 this monograph? This is where those statements came</p> <p>6 from.</p> <p>7 A I have seen the monograph, I don't</p> <p>8 specifically recall this page.</p> <p>9 Q Okay. Well, look at the bottom of it, that</p> <p>10 table. And do you see -- these are Group 1 agents, and</p> <p>11 IARC defines Group 1 agents as known human carcinogens;</p> <p>12 right?</p> <p>13 A Yes, correct.</p> <p>14 Q And it identifies, first of all, arsenic as a</p> <p>15 known human carcinogen, and it identifies tumor sites</p> <p>16 for which there is sufficient evidence of human</p> <p>17 carcinogenicity as lungs, skin, urinary bladder.</p> <p>18 Do you see that?</p> <p>19 A In the second column I see lungs, skin, yes,</p> <p>20 urinary bladder. Uh-huh.</p> <p>21 Q And a little bit further down it identifies</p> <p>22 chromium as a Group 1 carcinogenic.</p> <p>23 Do you see that?</p> <p>24 A I do.</p> <p>25 Q And it identifies the lung as a potential</p>	<p>1 conclusion about ovarian cancer has significant issues</p> <p>2 that I would argue with.</p> <p>3 Q That's not my question. My question is do you</p> <p>4 agree that asbestos can cause cancer in the ovary, like</p> <p>5 IARC says?</p> <p>6 MS. AHERN: Objection. Form. Asked and answered.</p> <p>7 THE WITNESS: I just said I don't agree that it</p> <p>8 causes ovarian cancer.</p> <p>9 BY MR. DEARING:</p> <p>10 Q Do you -- if you move over to the fourth</p> <p>11 column under asbestos, it describes the established</p> <p>12 mechanistic events that cause the cancer. And it says</p> <p>13 the asbestos causes "impaired fiber clearance leading</p> <p>14 to macrophage activation, inflammation, generation of</p> <p>15 reactive oxygen and nitrogen species, tissue injury,</p> <p>16 genotoxicity, aneuploidy and polyploidy epigenetic</p> <p>17 alteration, activation of signaling pathways,</p> <p>18 resistances to apoptosis."</p> <p>19 So do you agree asbestos can cause lung</p> <p>20 cancer?</p> <p>21 A Yes.</p> <p>22 Q Do you agree that that's the mechanism by</p> <p>23 which asbestos can cause lung cancer?</p> <p>24 MS. AHERN: Objection.</p> <p>25 THE WITNESS: I should clarify what I just said a</p>

21 (Pages 78 to 81)

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<p style="text-align: right;">Page 82</p> <p>1 moment ago using the term "cancer." And what I would  2 say is that asbestos is primary -- causes  3 mesotheliomas, which is a type of cancer but is very  4 different from adenocarcinoma or squamous cell  5 carcinoma of the lung, and which asbestos is -- plays  6 maybe a contributory role, but certainly not the major  7 role.  8 BY MR. DEARING:  9 Q Okay. So my question is do you believe that  10 asbestos can cause mesothelioma or other lung cancers  11 by the mechanism that's described in this table?  12 MS. AHERN: Objection. Form.  13 THE WITNESS: Well, I'm not an expert on  14 mesothelioma and asbestosis. However, I would agree  15 that asbestos causes mesothelioma -- pleural  16 mesothelioma and potentially these mechanisms might  17 explain it, but I haven't studied it.  18 BY MR. DEARING:  19 Q So you say that might be the mechanism, but  20 you just don't know?  21 A Well, I haven't studied it. I don't  22 specialize in asbestosis.  23 Q I'm not faulting you. I'm just saying you're  24 saying that could be, but you don't know. Does that  25 mean you don't have a concrete opinion on that, whether</p>	<p style="text-align: right;">Page 84</p> <p>1 BY MR. DEARING:  2 Q Are you aware of other cancers or do you have  3 knowledge to explain whether other cancers may be  4 caused by this mechanistic process described by IARC  5 pertaining to asbestos?  6 A Again, I mean, with established mechanistic  7 events, things like resistance to apoptosis, activation  8 of signaling pathways, epigenetic alteration,  9 genotoxicity, these are general mechanisms that have  10 been implicated in the development of cancer in  11 general.  12 Q So looking at this mechanism that's described  13 by IARC, it says, "Impaired fiber clearance leading to  14 macrophage activation."  15 Do you agree that macrophage activation is a  16 foreign-body response in the body?  17 MS. AHERN: Objection. Form.  18 THE WITNESS: Macrophages can be induced by a  19 variety of -- well, of course, you mentioned  20 foreign-body giant cell reaction, but other types of  21 inflammation can also induce the presence of  22 macrophages.  23 BY MR. DEARING:  24 Q And giant cell granulomas are an agglomeration  25 of macrophages; right?</p>
<p style="text-align: right;">Page 83</p> <p>1 that's the mechanism that causes mesothelioma?  2 A Well, these are the mechanisms that IARC  3 describes which, you know, may be reasonable. But,  4 again, I don't have direct personal experience with  5 that. So I can't confirm every one of these features.  6 Q Okay. It also suggests that asbestos causes  7 cancer in the larynx.  8 Do you agree that -- that that's true?  9 MS. AHERN: Objection. Form.  10 THE WITNESS: I really don't know about the  11 laryngeal carcinoma.  12 BY MR. DEARING:  13 Q It also says there are possibly other sites  14 where asbestos causes cancer -- the colorectum, the  15 pharynx, the stomach.  16 Do you have any opinion about whether asbestos  17 causes cancer in those organs?  18 A Again, these are areas that I'm not -- I have  19 no involvement with. So I can't really comment.  20 Q Are you aware of other cancers that are caused  21 by this mechanistic process that's described here by  22 IARC for asbestos?  23 MS. AHERN: Objection. Form.  24 THE WITNESS: Could you rephrase that question?  25 MR. DEARING: Sure.</p>	<p style="text-align: right;">Page 85</p> <p>1 A Well, in the tissue, they're referred to  2 histiocytes, but they're basically macrophages.  3 Q So a giant cell is a joined group of  4 macrophages; right?  5 A Correct.  6 Q So according to this mechanism described by  7 IARC, macrophage activation occurs, which appears to be  8 defined as inflammation.  9 Would you agree that that's what they mean  10 there by saying "inflammation"?  11 MS. AHERN: Objection. Form.  12 THE WITNESS: Well, as I said just a moment ago,  13 macrophage activation can occur with a variety of  14 inflammatory reactions, not just only foreign-body  15 giant cell.  16 BY MR. DEARING:  17 Q Okay. Macrophage activation is a type of  18 inflammation; right? Is that a fair statement?  19 A Not really. It's part of the inflammatory  20 reaction. There are other cells as well --  21 lymphocytes, plasma cells, eosinophils,  22 polymorphonuclear leukocytes. Macrophages are one type  23 of cell involved in inflammation.  24 Q And then do you agree that inflammation can  25 lead to the generation of reactive oxygen and nitrogen</p>



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<p style="text-align: right;">Page 86</p> <p>1 species?</p> <p>2 MS. AHERN: Objection. Form.</p> <p>3 BY MR. DEARING:</p> <p>4 Q Is that outside your specialty?</p> <p>5 A Again, I mean, I've read enough about that to</p> <p>6 know that, yes, macrophage activation could induce</p> <p>7 reactive oxygen species.</p> <p>8 Q And reactive nitrogen species.</p> <p>9 A And reactive nitrogen species.</p> <p>10 Q And can reactive oxygen species and reactive</p> <p>11 nitrogen species damage DNA?</p> <p>12 A Can it damage DNA? Yes.</p> <p>13 Q And damaging, DNA, of course, can cause</p> <p>14 uncontrolled proliferation of cells; correct?</p> <p>15 MS. AHERN: Objection. Form.</p> <p>16 THE WITNESS: Well --</p> <p>17 BY MR. DEARING:</p> <p>18 Q I know there's some steps in between, but I'm</p> <p>19 trying to speed this up.</p> <p>20 MS. AHERN: Same objection.</p> <p>21 THE WITNESS: Well, involvement -- interjection of</p> <p>22 a certain agent into DNA can cause DNA damage, that's</p> <p>23 true.</p> <p>24 BY MR. DEARING:</p> <p>25 Q I'm not talking about certain agents. I'm</p>	<p style="text-align: right;">Page 88</p> <p>1 BY MR. DEARING:</p> <p>2 Q So thank goodness you can have DNA damage</p> <p>3 without cancer, but you can't have cancer without DNA</p> <p>4 damage; right?</p> <p>5 MS. AHERN: Objection. Form.</p> <p>6 THE WITNESS: As far as I know, all cancers are</p> <p>7 part of -- part of the development of cancer is</p> <p>8 dependent on damage -- or I should say genotoxicity,</p> <p>9 which means damage in DNA in some form.</p> <p>10 BY MR. DEARING:</p> <p>11 Q And resistance to apoptosis can also be a</p> <p>12 result of DNA damage; right? That's part of the</p> <p>13 problem with cancer is the cells don't -- they lose</p> <p>14 their programmed ability to self-destruct; right?</p> <p>15 MS. AHERN: Objection. Form.</p> <p>16 THE WITNESS: That's one of the factors in</p> <p>17 carcinogenesis, one of the factors.</p> <p>18 BY MR. DEARING:</p> <p>19 Q But that resistance to apoptosis is a result</p> <p>20 of DNA damage; right?</p> <p>21 MS. AHERN: Objection. Form.</p> <p>22 THE WITNESS: Generally speaking, it's an</p> <p>23 activation of a suppressor gene called p53, maybe some</p> <p>24 other genes as well.</p> <p>25 ///</p>
<p style="text-align: right;">Page 87</p> <p>1 talking specifically about reactive oxygen species and</p> <p>2 reactive nitrogen species. Those agents can damage</p> <p>3 DNA; right?</p> <p>4 A Yes, they can.</p> <p>5 Q And then cells with damaged DNA can become</p> <p>6 cancer cells, can't they?</p> <p>7 MS. AHERN: Objection. Form.</p> <p>8 THE WITNESS: Not necessarily. Not all of them do.</p> <p>9 Some might.</p> <p>10 BY MR. DEARING:</p> <p>11 Q Well, would you agree that all cancers are</p> <p>12 borne out of some genetic disruption?</p> <p>13 MS. AHERN: Objection. Form.</p> <p>14 THE WITNESS: The issue is it plays a role in</p> <p>15 carcinogenesis. But DNA damage, in and of itself, does</p> <p>16 not invariably lead to malignant transformation.</p> <p>17 BY MR. DEARING:</p> <p>18 Q Right. But I'm asking the inverse of that</p> <p>19 question.</p> <p>20 You can't have cancer without original DNA</p> <p>21 damage; right?</p> <p>22 A That's --</p> <p>23 MS. AHERN: Objection. Form.</p> <p>24 THE WITNESS: DNA damage is part of the process of</p> <p>25 development of a carcinoma.</p>	<p style="text-align: right;">Page 89</p> <p>1 BY MR. DEARING:</p> <p>2 Q So as I mentioned, this is from 2009; right?</p> <p>3 Do you agree with me?</p> <p>4 A I think that's --</p> <p>5 Q The date is at the very bottom of the page.</p> <p>6 A Yeah.</p> <p>7 Q It's right under the table, actually.</p> <p>8 A I see it, 2009.</p> <p>9 Q Okay. So in 2009 IARC said, "Epidemiological</p> <p>10 evidence has increasingly shown an association" --</p> <p>11 A Where are we reading now?</p> <p>12 Q I'm sorry. The top of page 454, so the other</p> <p>13 page, very top.</p> <p>14 A Uh-huh.</p> <p>15 Q "Epidemiological evidence has</p> <p>16 increasingly shown an association for</p> <p>17 all forms of asbestos (chrysotile,</p> <p>18 crocidolite, amosite, tremolite,</p> <p>19 actinolite, and anthophyllite) with an</p> <p>20 increased risk of lung cancer and</p> <p>21 mesothelioma."</p> <p>22 Do you agree with that statement?</p> <p>23 A Yes.</p> <p>24 Q It goes on to say:</p> <p>25 "Although the potency differences</p>

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<p style="text-align: right;">Page 90</p> <p>1 with respect to lung cancer or 2 mesothelioma for fibers of various types 3 and dimensions are debated, the 4 fundamental conclusion is that all forms 5 of asbestos are carcinogenic to humans." 6 Do you agree with that? 7 MS. AHERN: Objection. Form. 8 THE WITNESS: Well, again, I'm not an expert on the 9 different types of asbestos. I would leave -- I would 10 defer that to an mineralogist to agree as to whether 11 all types, as they state here, are associated with 12 cancer. 13 BY MR. DEARING: 14 Q The next sentence says: 15 "Mineral substances, for example, 16 talc and vermiculite, that contain 17 asbestos should also be regarded as 18 carcinogenic to humans." 19 Do you agree with that statement? 20 A Well, that's -- 21 MS. AHERN: Objection. Form. 22 THE WITNESS: That's what IARC states. Again, I 23 don't agree with that, but that -- they state that, but 24 I don't agree with it. 25 ///</p>	<p style="text-align: right;">Page 92</p> <p>1 it applies in 2019? 2 A Well, if you read further down the paragraph, 3 you'll see that it says -- let's see, one, two, three, 4 four, five, six, seven, eight -- ten lines, it says: 5 "Cohort studies of women who were 6 heavily exposed to asbestos in the 7 workplace consistently report increased 8 risks of ovarian cancer, as in a study 9 of women in the UK who manufactured gas 10 masks during World War II." 11 Q Right. 12 A "Studies suggest asbestos can accumulate in 13 the ovaries of women who were exposed to it." 14 So you're talking about massive exposures of 15 asbestos in women who are occupationally exposed. The 16 numbers of cases, I looked at that, are very small 17 because most of people who worked in that industry were 18 men. 19 So, again, you're referring to small numbers 20 of cases, extremely heavy exposure to asbestos that 21 allows them to come to that conclusion, which is what I 22 dispute. 23 Furthermore, I think there's a significant 24 risk that cases called ovarian cancer -- you'll notice 25 that there's no pathologist in the -- in the group in</p>
<p style="text-align: right;">Page 91</p> <p>1 BY MR. DEARING: 2 Q If a mineral substance contains carcinogenic 3 asbestos, doesn't that make that mineral substance 4 carcinogenic? 5 MS. AHERN: Objection. Form. 6 THE WITNESS: We have no idea how much asbestos is 7 in there. It might be a totally minute amount, that 8 there's a contaminant that doesn't have any 9 relationship to the development of cancer. 10 BY MR. DEARING: 11 Q Well, you would agree with me that the FDA has 12 determined that there's no safe level of asbestos 13 exposure; right? 14 MS. AHERN: Objection. Form. 15 THE WITNESS: As I said earlier, when it comes to 16 the specifics of the composition of asbestos or, for 17 that matter, talc, I would defer to a mineralogist. 18 BY MR. DEARING: 19 Q Then the next sentence is what I read to you 20 already: 21 "Sufficient evidence is now 22 available in 2009 to show that asbestos 23 also causes cancer of the larynx and of 24 the ovary." 25 And you disagree with that statement, even as</p>	<p style="text-align: right;">Page 93</p> <p>1 this -- in that statement that we read earlier, no 2 pathologist in the IARC group. And I would dispute the 3 fact that these are all carcinomas of the ovary. They 4 may be mesotheliomas that were misclassified. 5 Q Okay. Do you believe asbestos can cause 6 mesothelioma of the ovary? 7 A Well, I'd have -- 8 MS. AHERN: Objection. Form. 9 THE WITNESS: I'd have to, again, review the data. 10 I can tell you I hardly ever see, and there were hardly 11 any reports of, mesotheliomas involving the ovary. 12 BY MR. DEARING: 13 Q The last sentence you just read, "Studies 14 suggest that asbestos can accumulate in the ovaries of 15 women who are exposed to it," do you agree or disagree 16 with that? 17 A Well, let's look at the reference that they're 18 talking about. 19 Q It's the Heller study. 20 A Heller study. 21 Q Drs. Heller, Gordon, Westhoff, Gerber. 22 A Yeah, maybe we could look at that and see what 23 they say. 24 Q Okay. Well, you know, in that study, they -- 25 they used transmission electron microscopy to digest</p>

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<p style="text-align: right;">Page 94</p> <p>1 tissue to measure the burden count of asbestos fibers</p> <p>2 in the tissue.</p> <p>3 Do you know that about that study?</p> <p>4 MS. AHERN: Objection. Form.</p> <p>5 THE WITNESS: I'd like to see the study.</p> <p>6 BY MR. DEARING:</p> <p>7 Q Okay. So you have no opinion about that right</p> <p>8 not without seeing the study that --</p> <p>9 A Well, it's been a long time --</p> <p>10 Q Let me finish the question, please.</p> <p>11 A Yeah, sorry.</p> <p>12 Q So you have no opinion about whether asbestos</p> <p>13 can accumulate in the ovaries of women who are exposed</p> <p>14 to it?</p> <p>15 A I said I'd like to see the study.</p> <p>16 Q That doesn't answer my question. You either</p> <p>17 have an opinion or you don't.</p> <p>18 MS. AHERN: Objection. Form.</p> <p>19 THE WITNESS: My answer is I can't come to an</p> <p>20 opinion until I've seen the study.</p> <p>21 BY MR. DEARING:</p> <p>22 Q Okay. And you don't know whether you've seen</p> <p>23 the study before?</p> <p>24 A I have seen the study, but I'd like to see it</p> <p>25 again. It's been a while.</p>	<p style="text-align: right;">Page 96</p> <p>1 MS. AHERN: Objection. Form. Asked and answered.</p> <p>2 THE WITNESS: I'll just repeat what I said before.</p> <p>3 All I'm referring to is what they say talc is in the</p> <p>4 various studies. I don't know all the details of the</p> <p>5 composition of the talcum powder that they use.</p> <p>6 BY MR. DEARING:</p> <p>7 Q Since you have an opinion that talc cannot</p> <p>8 cause any type of inflammatory reaction that could</p> <p>9 cause ovarian cancer, don't you think it's important to</p> <p>10 know something about whether that talc is platy talc or</p> <p>11 asbestiform fibrous talc, or what type of talc it is?</p> <p>12 A No. It doesn't matter. Whatever it is hasn't</p> <p>13 been shown to form ovarian cancer.</p> <p>14 Q Is it your opinion that asbestos exposed to</p> <p>15 ovaries doesn't cause cancer either?</p> <p>16 A I'm not convinced of it at this point. I'd</p> <p>17 like to see more studies.</p> <p>18 Q Okay. Is it biologically plausible that</p> <p>19 asbestos could cause ovarian cancer?</p> <p>20 A Biologically plausible? Again, to me, it's --</p> <p>21 it has to be seen. And I haven't seen that yet. I'd</p> <p>22 like to see more studies, and then I could tell you</p> <p>23 whether I think it's biologically plausible or not.</p> <p>24 Q So you don't know whether it's biologically</p> <p>25 plausible, as you sit here right now?</p>
<p style="text-align: right;">Page 95</p> <p>1 Q Okay. All right. Do you have any opinion</p> <p>2 about whether Johnson &amp; Johnson baby powder or Shower</p> <p>3 to Shower product has any form of asbestos in it?</p> <p>4 A I'll repeat what I said earlier that I'm just</p> <p>5 talking about the talc that I read. I don't know</p> <p>6 what's in their -- what's in their bottles of baby</p> <p>7 powder or Shower -- whatever. I would depend on -- I</p> <p>8 would depend really -- because it's complex. It's</p> <p>9 complex. It's debated. There are subtle differences</p> <p>10 between how much, what the type of asbestos is.</p> <p>11 So I would really have to defer to a</p> <p>12 mineralogist to answer that question.</p> <p>13 Q Are you familiar with the term "asbestiform</p> <p>14 fibrous talc"?</p> <p>15 MS. AHERN: Objection. Form.</p> <p>16 THE WITNESS: I've heard it mentioned.</p> <p>17 BY MR. DEARING:</p> <p>18 Q Do you feel like you know enough about it to</p> <p>19 discuss it?</p> <p>20 A No.</p> <p>21 Q Based on what you've read -- and maybe you</p> <p>22 haven't read anything about this -- do you have an</p> <p>23 opinion about whether Johnson &amp; Johnson's baby powder</p> <p>24 or Shower to Shower products have asbestiform fibrous</p> <p>25 talc in them?</p>	<p style="text-align: right;">Page 97</p> <p>1 A I'm saying I'd like to see more studies to be</p> <p>2 more convinced that it might be biologically plausible.</p> <p>3 At this point, I'm not convinced.</p> <p>4 Q That doesn't answer my question. I know you</p> <p>5 would like to see more studies.</p> <p>6 My question is, do you have an opinion one way</p> <p>7 or the other whether asbestos exposure to ovaries -- do</p> <p>8 you have an opinion one way or the other whether it's</p> <p>9 biologically plausible that asbestos can cause ovarian</p> <p>10 cancer? Just do you have an opinion?</p> <p>11 If you don't have an opinion, that's fine. I</p> <p>12 just want to know.</p> <p>13 A When I repeat it --</p> <p>14 MS. AHERN: Objection. Form.</p> <p>15 THE WITNESS: -- I'm repeating what I said earlier.</p> <p>16 BY MR. DEARING:</p> <p>17 Q I know you want to see studies.</p> <p>18 Does that mean you don't have an opinion?</p> <p>19 A At this point, I'm not convinced that it's</p> <p>20 biologically plausible to cause ovarian cancer. I want</p> <p>21 to see something that shows me evidence of that, and I</p> <p>22 don't see it.</p> <p>23 Q Well, what would you want to see that would</p> <p>24 show you evidence that it's biologically plausible that</p> <p>25 ovarian -- that asbestos exposure can cause ovarian</p>

25 (Pages 94 to 97)

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<p style="text-align: right;">Page 98</p> <p>1 cancer?</p> <p>2 A It would be nice to see asbestos in ovaries</p> <p>3 causing a fibrous reaction, maybe seeing some</p> <p>4 ferruginous bodies, which are very characteristic of</p> <p>5 asbestos exposure in patients who have ovarian cancer.</p> <p>6 Q And while we're talking about this, what would</p> <p>7 you expect to see or want to see regarding biologic</p> <p>8 plausibility of talc causing ovarian cancer?</p> <p>9 A Well, we kind of --</p> <p>10 Q Same thing?</p> <p>11 A -- discussed that earlier that with -- I'd</p> <p>12 like to see a chronic foreign-body giant cell</p> <p>13 granulomatous reaction, something to indicate that it's</p> <p>14 biologically active and not just sitting there, say, as</p> <p>15 a contaminant.</p> <p>16 Q Okay. That's all you would want to see?</p> <p>17 A I'd like to see ovarian cancer associated with</p> <p>18 it, an ovarian cancer in which these -- this is</p> <p>19 associated with what I just described.</p> <p>20 Q How would you make the connection between a</p> <p>21 foreign-body response to talc in the ovary and cancer</p> <p>22 of the ovary? If you saw the foreign-body reaction</p> <p>23 that you're saying you want to see, is that enough to</p> <p>24 say, "Well, if that's there, it may be able to cause</p> <p>25 cancer"?</p>	<p style="text-align: right;">Page 100</p> <p>1 herpes simplex virus type 2, was thought to cause</p> <p>2 cervical cancer. There were electron micrographs</p> <p>3 showing HSV-2 particles in cervical cancer.</p> <p>4 There were zero epidemiologic studies</p> <p>5 confirming that HSV caused cervical cancer with</p> <p>6 relative risks like ten, much higher than you see with</p> <p>7 talc, and it was all wrong. As you said, it's -- you</p> <p>8 know HPV causes it, not herpes.</p> <p>9 So just the presence of that in the ovarian</p> <p>10 tumor doesn't mean that it causes cancer.</p> <p>11 MR. DEARING: Right. I move to strike as</p> <p>12 nonresponsive.</p> <p>13 BY MR. DEARING:</p> <p>14 Q My question is, what do you need to see</p> <p>15 between the foreign-body response that you're</p> <p>16 describing and the cancer to link the two? That's the</p> <p>17 question.</p> <p>18 MS. AHERN: Objection. Form.</p> <p>19 BY MR. DEARING:</p> <p>20 Q What do you need to see?</p> <p>21 MS. AHERN: Objection. Form.</p> <p>22 THE WITNESS: I'd like to see fulfillment of the</p> <p>23 various criteria that we've talked about before,</p> <p>24 Bradford Hill, to really say that all the various</p> <p>25 studies, not just biologic plausibility but strength of</p>
<p style="text-align: right;">Page 99</p> <p>1 A Not at all.</p> <p>2 MS. AHERN: Objection. Form.</p> <p>3 THE WITNESS: No, not at all.</p> <p>4 MR. DEARING: Okay.</p> <p>5 THE WITNESS: And I'll give you a specific example</p> <p>6 of something -- where that kind of information was very</p> <p>7 misleading.</p> <p>8 I was involved, and I have been involved for</p> <p>9 the last 15 years, with HPV and cervical --</p> <p>10 BY MR. DEARING:</p> <p>11 Q Excuse me, Doctor. I don't mean to cut you</p> <p>12 off. I know about HPV virus. I don't need to talk</p> <p>13 about that.</p> <p>14 MS. AHERN: Let him answer, and then you can object</p> <p>15 as nonresponsive.</p> <p>16 MR. DEARING: Well, he's clearly not, and I have a</p> <p>17 limited amount of time.</p> <p>18 BY MR. DEARING:</p> <p>19 Q What I'm saying is, what do you say about</p> <p>20 talc?</p> <p>21 A I'm going to talk about why seeing the</p> <p>22 presence of a substance in the ovary with the cancer</p> <p>23 doesn't mean that it's causing the cancer.</p> <p>24 And I was -- before you interrupted me, I was</p> <p>25 going to say that, in the 1960s, '70s, and '80s, HSV-2,</p>	<p style="text-align: right;">Page 101</p> <p>1 association from epidemiologic studies, dose response,</p> <p>2 consistency, the various factors that Bradford Hill</p> <p>3 requires to show causality. That's what I want to see,</p> <p>4 and I haven't seen that.</p> <p>5 BY MR. DEARING:</p> <p>6 Q So there's nothing pathologically you want to</p> <p>7 see?</p> <p>8 A Well, that might explain --</p> <p>9 MS. AHERN: Objection. Form.</p> <p>10 THE WITNESS: That may be one factor that could be</p> <p>11 considered.</p> <p>12 BY MR. DEARING:</p> <p>13 Q So back to my question.</p> <p>14 What pathologically you would expect to see in</p> <p>15 tissue such that you would link the formation of</p> <p>16 foreign-body response to the cancer?</p> <p>17 MS. AHERN: Objection. Form.</p> <p>18 THE WITNESS: I would like to -- I haven't ever</p> <p>19 seen it. Okay. So I don't know what I would expect.</p> <p>20 It's a completely hypothetical question. I'd have to</p> <p>21 see what I see, and then I could tell you an answer.</p> <p>22 BY MR. DEARING:</p> <p>23 Q Are you aware that IARC also classified</p> <p>24 asbestiform talc fibers as carcinogenic?</p> <p>25 A Are you distinguishing that from just other</p>

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<p style="text-align: right;">Page 102</p> <p>1 types of asbestos?</p> <p>2 Q Asbestiform talc fibers are not asbestos.</p> <p>3 A I'm sorry. Repeat your question.</p> <p>4 Q Yes. I am distinguishing those two. And if</p> <p>5 you don't know this and I'm outside of your wheelhouse,</p> <p>6 just tell me and I'll move on.</p> <p>7 A Yeah.</p> <p>8 Q Asbestiform talc fibers --</p> <p>9 A Oh, okay.</p> <p>10 Q -- so not asbestos.</p> <p>11 Are you aware that IARC has identified</p> <p>12 asbestiform talc fibers as carcinogenic to humans?</p> <p>13 MS. AHERN: Objection. Form.</p> <p>14 THE WITNESS: I'm not aware of that.</p> <p>15 MR. DEARING: Would that fact affect your opinion</p> <p>16 about whether talc can cause ovarian cancers?</p> <p>17 THE WITNESS: No.</p> <p>18 MS. AHERN: Objection. Form.</p> <p>19 BY MR. DEARING:</p> <p>20 Q Have you read the 2012 IARC Monograph?</p> <p>21 A You'd have to show it to me. I don't recall.</p> <p>22 Q Well, it's on your reference list.</p> <p>23 A Yeah. Well, I'd have to see it again.</p> <p>24 Q Okay.</p> <p>25 ///</p>	<p style="text-align: right;">Page 104</p> <p>1 Containing Asbestiform Fibres"?</p> <p>2 A Where am I? 230?</p> <p>3 Q I think you're on 231.</p> <p>4 A Oh, yeah.</p> <p>5 Q It says:</p> <p>6 "Talc particles are normally</p> <p>7 plate-like. These particles, when</p> <p>8 viewed on edge under the microscope, in</p> <p>9 bulk samples or on air filters, may</p> <p>10 appear to be fibers and have been</p> <p>11 misidentified as such. Talc may also</p> <p>12 form true mineral fibers that are</p> <p>13 asbestiform in habit. In some talc</p> <p>14 deposits, tremolite, anthophyllite, and</p> <p>15 actinolite may occur. Talc containing</p> <p>16 asbestiform fibers is a term that has</p> <p>17 been used inconsistently in the</p> <p>18 literature. In some contexts, it</p> <p>19 applies to talc containing asbestiform</p> <p>20 fibers of talc."</p> <p>21 Do you feel like you have an understanding of</p> <p>22 asbestiform talc fibers based on that explanation of</p> <p>23 what they are to talk more about them, or are we still</p> <p>24 outside of your expertise?</p> <p>25 A I like the term where it says "inconsistently</p>
<p style="text-align: right;">Page 103</p> <p>1 (The document referenced below was</p> <p>2 marked Deposition Exhibit 5 for</p> <p>3 identification and is appended hereto.)</p> <p>4 BY MR. DEARING:</p> <p>5 Q Doctor, I'm marking as Exhibit 5 a portion of</p> <p>6 the 2012 Monograph, and the reason is it's several</p> <p>7 hundred pages long and I'm trying to save some trees.</p> <p>8 But here is the portion that I want to talk to</p> <p>9 you about. First of all --</p> <p>10 MS. AHERN: I'm sorry, one second. Could I get a</p> <p>11 copy? Thank you.</p> <p>12 BY MR. DEARING:</p> <p>13 Q So obviously the cover there identifies this</p> <p>14 as an IARC Monograph, and it's addressing arsenic,</p> <p>15 metals, fibers, and dust. And it's Volume 100C.</p> <p>16 Do you see that?</p> <p>17 A Yes.</p> <p>18 Q And this is the one that you referenced in</p> <p>19 your reference list; right?</p> <p>20 A Yes.</p> <p>21 Q And you think you have seen this before?</p> <p>22 You've read this?</p> <p>23 A Yes.</p> <p>24 Q If you would, turn to page 230.</p> <p>25 Do you see the section entitled "Talc</p>	<p style="text-align: right;">Page 105</p> <p>1 in the literature."</p> <p>2 Q Right.</p> <p>3 A So if it's inconsistently in the literature,</p> <p>4 I, as not a mineralogist, would have a lot of trouble</p> <p>5 dissecting all that out.</p> <p>6 Q It's inconsistent in the literature because</p> <p>7 some authors treat asbestiform talc as asbestos, and</p> <p>8 there's some confusion in the name. They should have</p> <p>9 named it something else, but that's the confusion</p> <p>10 they're talking about.</p> <p>11 MS. AHERN: Objection to the characterization.</p> <p>12 BY MR. DEARING:</p> <p>13 Q Anyway, we'll move on to the human exposure</p> <p>14 section, page 232. The subheading is "Human Exposure."</p> <p>15 A Yes.</p> <p>16 Q And it says -- and this explains -- this is</p> <p>17 the way IARC explains exposures and explains</p> <p>18 carcinogenesis of the identified carcinogens is they</p> <p>19 first talk about how humans get exposed to it.</p> <p>20 And they say here that:</p> <p>21 "Consumer products (cosmetics,</p> <p>22 pharmaceuticals) are the primary source</p> <p>23 of exposure to talc for the general</p> <p>24 population. Inhalation and dermal</p> <p>25 contact, (i.e. through perineal</p>

27 (Pages 102 to 105)



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<p style="text-align: right;">Page 106</p> <p>1 application of talcum powders) are the</p> <p>2 primary routes of exposure."</p> <p>3 Do you agree with that statement that</p> <p>4 inhalation and dermal contact, such as through perineal</p> <p>5 application of talcum powders, is the primary route of</p> <p>6 exposure for talc for humans?</p> <p>7 MS. AHERN: Objection. Form.</p> <p>8 THE WITNESS: As far as I know, inhalation and</p> <p>9 perineal exposure are the main contacts.</p> <p>10 BY MR. DEARING:</p> <p>11 Q Right. In -- when they describe that</p> <p>12 exposure, IARC is describing exposure to the general</p> <p>13 population; right? That's what it says right above</p> <p>14 it --</p> <p>15 A Yeah.</p> <p>16 Q -- "exposure to the general population"?</p> <p>17 A That's what it says.</p> <p>18 Q Okay. That's all I'm going to ask you about</p> <p>19 that.</p> <p>20 Do you agree with the statement that "Patients</p> <p>21 with chronic aspirin, nonsteroidal anti-inflammatory</p> <p>22 drugs, or acetaminophen use have a reduced risk of</p> <p>23 ovarian -- epithelial ovarian cancer"?</p> <p>24 MS. AHERN: Objection.</p> <p>25 MR. DEARING: That was terrible. Let me start all</p>	<p style="text-align: right;">Page 108</p> <p>1 A Absolutely not.</p> <p>2 Q What is retrograde menstruation?</p> <p>3 A Retrograde menstruation occurs in women when</p> <p>4 they have, at the time of menses, instead of the</p> <p>5 breakdown of the lining of the uterus, which is the</p> <p>6 endometrium, passing through the cervix, the vagina,</p> <p>7 and going as we normally -- as normally occurs in</p> <p>8 menstruation, goes the other way and goes through the</p> <p>9 fallopian tubes to the peritoneal cavity.</p> <p>10 Q And you agree that 90 percent of women with</p> <p>11 healthy fallopian tubes experience retrograde</p> <p>12 menstruation?</p> <p>13 MS. AHERN: Objection. Form.</p> <p>14 THE WITNESS: I don't know what the percentage is,</p> <p>15 but I'm sure it's frequent.</p> <p>16 BY MR. DEARING:</p> <p>17 Q In your report on page 9, you have a short</p> <p>18 discussion here about endometriosis and endometrioid</p> <p>19 carcinomas.</p> <p>20 A Let me get there. Okay. Page 9.</p> <p>21 Q Right. You say in the third sentence:</p> <p>22 "The precise origin of</p> <p>23 endometriosis has not been conclusively</p> <p>24 established. Proposed mechanisms</p> <p>25 include retrograde menstrual flow and in</p>
<p style="text-align: right;">Page 107</p> <p>1 over. Good grief.</p> <p>2 BY MR. DEARING:</p> <p>3 Q Do you agree that patients with chronic</p> <p>4 aspirin, nonsteroidal anti-inflammatory drug, or</p> <p>5 acetaminophen use have a reduced risk of epithelial</p> <p>6 ovarian cancer?</p> <p>7 A So you're referring to the epidemiology</p> <p>8 studies, I assume?</p> <p>9 Q There are several studies, yes.</p> <p>10 A Yeah. Well, from what I recall, and it's been</p> <p>11 a while, they are inconsistent. Some show that they</p> <p>12 decrease risk. And some, specifically the NSAIDs, as I</p> <p>13 remember, did not show there was a reduced risk of</p> <p>14 ovarian cancer.</p> <p>15 Q Do you have an opinion professionally?</p> <p>16 A Well --</p> <p>17 MS. AHERN: Objection. Form.</p> <p>18 THE WITNESS: -- as I said, I'm not an</p> <p>19 epidemiologist, I'm not going to get into the</p> <p>20 nitty-gritty of it, but just based on those studies, I</p> <p>21 would say that it's not -- it's inconsistent.</p> <p>22 BY MR. DEARING:</p> <p>23 Q Do you believe that talc can migrate from the</p> <p>24 perineum through a woman's reproductive tract to the</p> <p>25 ovaries?</p>	<p style="text-align: right;">Page 109</p> <p>1 situ development in the peritoneum</p> <p>2 through a process of metaplasia. Other</p> <p>3 mechanisms, including development of</p> <p>4 embryonic rests, have also been invoked.</p> <p>5 Most cases are best accounted for by</p> <p>6 retrograde menstruation, that's</p> <p>7 endometrial tissue expelled at the time</p> <p>8 of menstruation which passes through the</p> <p>9 fallopian tubes and implants on the</p> <p>10 ovary or other sites in the peritoneal</p> <p>11 cavity."</p> <p>12 Now, I assume, because you put this in your</p> <p>13 report, that's what you believe causes endometriosis.</p> <p>14 Is that right?</p> <p>15 MS. AHERN: Objection form.</p> <p>16 THE WITNESS: Yes, that's correct.</p> <p>17 BY MR. DEARING:</p> <p>18 Q But you acknowledge that has not conclusively</p> <p>19 established; right?</p> <p>20 A Generally -- it's generally thought to be the</p> <p>21 case.</p> <p>22 Q Right. But you write, "The precise origin of</p> <p>23 endometriosis has not been conclusively established."</p> <p>24 Right?</p> <p>25 A True.</p>

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<p style="text-align: right;">Page 110</p> <p>1 Q Does that mean other gynecologic pathologists</p> <p>2 disagree with you on that mechanism?</p> <p>3 MS. AHERN: Objection to form. Which mechanism?</p> <p>4 BY MR. DEARING:</p> <p>5 Q Is that what you mean by that?</p> <p>6 A Yeah.</p> <p>7 Q That endometriosis is caused by this process</p> <p>8 that you just described.</p> <p>9 A In other words, that endometriosis can be</p> <p>10 caused either by retrograde menstruation, metaplasia,</p> <p>11 or from embryonic rest. That covers it all.</p> <p>12 Q Okay. I want to put a diagram up, just</p> <p>13 because this makes it easier for me to talk about it.</p> <p>14 I can hand you one if you prefer, if it is easier to</p> <p>15 see, but -- I have lots of them.</p> <p>16 MS. AHERN: Thank you.</p> <p>17 THE WITNESS: Might as well take advantage of your</p> <p>18 generosity. Okay.</p> <p>19 BY MR. DEARING:</p> <p>20 Q So now using this diagram to describe this</p> <p>21 retrograde menstruation that you're talking about.</p> <p>22 A Uh-huh.</p> <p>23 Q So what you're saying is that the</p> <p>24 endometrium -- the endometrial tissues expelled during</p> <p>25 menstruation. Can you show me on your diagram, and</p>	<p style="text-align: right;">Page 112</p> <p>1 peritoneal cavity as well.</p> <p>2 Q When that reverse flow transports that</p> <p>3 endometrial tissue, does it pick up anything else when</p> <p>4 it goes?</p> <p>5 MS. AHERN: Objection. Form.</p> <p>6 BY MR. DEARING:</p> <p>7 Q Anything else that might be in that cavity?</p> <p>8 Any other cells?</p> <p>9 MS. AHERN: Objection. Form.</p> <p>10 THE WITNESS: There are no other cells. There's</p> <p>11 just the endometrium.</p> <p>12 BY MR. DEARING:</p> <p>13 Q What if there were bacterium in that area?</p> <p>14 Would the retrograde menstruation pick up the bacterium</p> <p>15 and deliver them to the ovaries with the tissue?</p> <p>16 A Well, certainly, women who have pelvic</p> <p>17 inflammatory disease, sexually transmitted disease, it</p> <p>18 involves the fallopian tubes. So somehow or another,</p> <p>19 the bacteria get there. Now, whether they come by</p> <p>20 lymphatics, I don't know. It's usually thought to be</p> <p>21 through lymphatics, not necessarily retrograde</p> <p>22 menstruation.</p> <p>23 Q Okay. My question is, if there were other</p> <p>24 materials in that tissue that's being transported,</p> <p>25 whether it's bacteria, whether it's foreign material,</p>
<p style="text-align: right;">Page 111</p> <p>1 then I'll repeat it here, where that tissue is coming</p> <p>2 from that's being expelled?</p> <p>3 A Yeah. It's coming from this little -- where</p> <p>4 it says "uterus."</p> <p>5 Q Right.</p> <p>6 A It's like a V.</p> <p>7 Q Uh-huh.</p> <p>8 A That's the lining of the uterine cavity,</p> <p>9 endometrial tissue.</p> <p>10 Q Okay.</p> <p>11 A And that's what breaks down and is expelled.</p> <p>12 Q So this area that I'm circling -- and I know</p> <p>13 this is not a three-dimensional diagram, but</p> <p>14 essentially it's the lining of the uterus that's being</p> <p>15 expelled; right?</p> <p>16 A That's correct.</p> <p>17 Q So you are saying during retrograde</p> <p>18 menstruation, this lining is expelled in the</p> <p>19 endometrium and then passes through the fallopian</p> <p>20 tubes, out the fimbriated end of the fallopian tube, to</p> <p>21 the ovary?</p> <p>22 MS. AHERN: Objection. Form.</p> <p>23 BY MR. DEARING:</p> <p>24 Q Am I stating that correctly?</p> <p>25 A That is -- yes. And other parts of the</p>	<p style="text-align: right;">Page 113</p> <p>1 don't you think -- or don't you agree that it could</p> <p>2 also be picked up and transported through the fallopian</p> <p>3 tubes to the ovaries?</p> <p>4 MS. AHERN: Objection. Form.</p> <p>5 THE WITNESS: It is complete speculation. I have</p> <p>6 no idea.</p> <p>7 BY MR. DEARING:</p> <p>8 Q You also state in your report that --</p> <p>9 A Back to the report. Specific page?</p> <p>10 Q Yes. Well --</p> <p>11 A Tell me where we are.</p> <p>12 Q I don't remember where I read it, and we can</p> <p>13 look for it in a minute, but let me just ask you the</p> <p>14 question.</p> <p>15 Do you agree that the epidemiological data</p> <p>16 indicate a protective effect of tubal ligations against</p> <p>17 ovarian cancer in general and an even stronger</p> <p>18 protective effect for endometrioid and clear cell</p> <p>19 carcinomas, which are sometimes associated with</p> <p>20 endometriosis?</p> <p>21 MS. AHERN: Objection.</p> <p>22 THE WITNESS: It reduces the risk of those,</p> <p>23 specifically endometrioid and clear cell, yes.</p> <p>24 BY MR. DEARING:</p> <p>25 Q Doesn't the epidemiological data also evidence</p>

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<p>1 a protective effect of ovarian cancers in general, all 2 histologic types of ovarian cancer, by tubal ligation? 3 MS. AHERN: Objection. Form. 4 THE WITNESS: I'm not sure -- there's data for 5 high-grade serous carcinoma. I'm not aware of data for 6 low-grade serous carcinoma. I'm not aware of data on 7 mucinous. I'm not aware of that. But for other -- 8 certainly high-grade serous carcinoma. 9 BY MR. DEARING: 10 Q Would you agree that high-grade serous 11 carcinomas make up about 80 percent of the ovarian 12 cancers? 13 A Yes. But I should add, as I put in my report, 14 that's not the only explanation. You're implying that 15 retrograde menstruation is what -- has reduced the risk 16 of high-grade serous carcinoma. I think there's 17 another statement in there that I made which indicates 18 that tubal ligation has been demonstrated in both 19 humans and animals to reduce or make that epithelium on 20 the fimbriated end of the tube more quiescent, meaning 21 less proliferation, less likelihood of mutations 22 occurring. And perhaps that's another mechanism that 23 reduces the risk of high-grade serous carcinoma. 24 Q I don't remember seeing that in your report, 25 but you do say, "Also supportive of this" -- and I'm on</p>	<p>1 carcinoma than for high-grade serous 2 carcinoma, presumably because tubal 3 ligation interrupts the retrograde 4 passage of endometrial tissue from the 5 uterus to the peritoneal cavity." 6 A Correct, but you have to keep reading. 7 Q "However, this mechanism does 8 not fit well with the development of 9 high-grade serous carcinoma, which is 10 now thought to derive from a precursor 11 lesion in the fimbriated end (the most 12 distal portion) of the fallopian tube, 13 which is in close contact with the 14 ovary." 15 I understand that, and I'm going to talk a lot 16 about -- 17 A Read the next sentence. 18 Q Okay. 19 A "Importantly, Tiourin, et al., 20 demonstrated in humans and mouse models 21 'that tubal ligations induces quiescence 22 of distal fallopian tube epithelium' by 23 decreasing the number and proliferation 24 of progenitor cells in that region, 25 which can explain the slight reduction</p>
Page 115	Page 117
<p>1 page 9, near the bottom of that paragraph. 2 "Also supportive of this hypothesis 3 are epidemiologic data that indicate the 4 protective effect for tubal ligation is 5 stronger for endometrioid and clear cell 6 carcinoma than for high-grade serous 7 carcinoma" -- 8 A I'm sorry. Could you just tell me where you 9 are reading again? I want to make sure you're right. 10 Q Sure. It is middle of that page -- 11 A "This suggests"? 12 Q -- bottom of the paragraph. 13 A Is that -- 14 Q Below "this suggests." 15 A Okay. "This suggests." Okay. 16 Q "Also supportive" -- 17 A Okay. Got you. 18 Q "Also supportive of this hypothesis" -- and 19 you're talking about this retrograde menstruation that 20 delivers endometrial tissue the ovary? 21 A Right. 22 Q "Also supportive of this hypothesis 23 are epidemiologic data that indicate the 24 protective effect for tubal ligation is 25 stronger for endometrioid and clear cell</p>	<p>1 in the risk of high-grade serous 2 carcinoma associated with this 3 procedure." 4 Q Okay. But you agree with me that 5 epidemiologic data shows a protective effect for 6 high-grade serous carcinoma in particular for women who 7 have undergone tubal ligations? 8 MS. AHERN: Objection. Form. 9 THE WITNESS: Yes. Slightly less than it is for 10 endometrioid and clear cell carcinoma. 11 BY MR. DEARING: 12 Q And for endometrial -- endometrioid and clear 13 cell carcinomas, it's a significant reduction in risk, 14 isn't it? 15 A I don't -- 16 Q Tubal ligation. 17 A Yes, it definitely plays a role. 18 Q And it makes perfect sense because, if you 19 occlude the tubes, nothing can pass through them; 20 right? 21 MS. AHERN: Objection. 22 THE WITNESS: Right. 23 How we doing with our bladders? 24 MS. AHERN: Do you need to go? 25 THE WITNESS: I drank too much coffee.</p>

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<p style="text-align: right;">Page 118</p> <p>1 MR. DEARING: Want to take a break?</p> <p>2 THE WITNESS: Yeah. Would that be okay?</p> <p>3 MR. DEARING: Absolutely. Anytime. Please tell</p> <p>4 me. I get carried away.</p> <p>5 VIDEO OPERATOR BROWN: Time is now 11:59. Going</p> <p>6 off the record.</p> <p>7 (Lunch recess taken.)</p> <p>8 VIDEO OPERATOR BROWN: Okay. Time is now 1:02.</p> <p>9 Back on the record.</p> <p>10 BY MR. DEARING:</p> <p>11 Q Doctor, you mentioned a few minutes ago -- a</p> <p>12 while ago about your textbook that you edited.</p> <p>13 It's called "Blaustein's" --</p> <p>14 A -- "Pathology of the Female Genital Tract."</p> <p>15 Q And you're the primary editor of that</p> <p>16 textbook; is that right?</p> <p>17 A I was until the last edition. I had two</p> <p>18 junior people join me, and they're doing that with me</p> <p>19 on this current edition that we're working on.</p> <p>20 Q What is the last edition that was published?</p> <p>21 A The sixth edition.</p> <p>22 Q And how many editions have you edited?</p> <p>23 A Third, fourth, and fifth by myself. Sixth</p> <p>24 with the two of them, and now the seventh with these</p> <p>25 two people.</p>	<p style="text-align: right;">Page 120</p> <p>1 Q Sure.</p> <p>2 So you've never actually seen the flow take</p> <p>3 place, obviously. Have you seen any evidence that that</p> <p>4 flow takes place that makes you think it exists?</p> <p>5 A Well, I've seen in microscopic slides of the</p> <p>6 fallopian tube taken out at the time a woman is</p> <p>7 menstruating, seen collections of blood and broken-down</p> <p>8 endometrium within the tubal lumen.</p> <p>9 Q Okay. So retrograde menstruation takes place</p> <p>10 during a woman's regular menstrual cycle, or is it some</p> <p>11 other time during that --</p> <p>12 A No, during the time of the menstrual cycle.</p> <p>13 Q So the menstrual fluid is flowing both ways at</p> <p>14 the same time?</p> <p>15 A Well, conceivably, yes. It's going out in the</p> <p>16 normal pathway, but also collections of the same kind</p> <p>17 of material can be seen in the lumen of the fallopian</p> <p>18 tube. Not often, but we've seen it.</p> <p>19 Q Is it your testimony that the only way that</p> <p>20 those endometrial cells could get to the lumen of the</p> <p>21 fallopian tube or to the ovaries is by this retrograde</p> <p>22 menstruation?</p> <p>23 MS. AHERN: Objection to form.</p> <p>24 THE WITNESS: Yeah. I can't imagine how they would</p> <p>25 get there any other way.</p>
<p style="text-align: right;">Page 119</p> <p>1 Q And in addition to editing the textbook, have</p> <p>2 you also authored chapters within the textbook?</p> <p>3 A Yes, I have.</p> <p>4 Q And who is the intended audience for that</p> <p>5 textbook? Is it for medical students? Doctors? What?</p> <p>6 A Yes.</p> <p>7 Q Anybody that's interested?</p> <p>8 A Right. Residents, fellows, gynecologists,</p> <p>9 pathologists in practice, medical students.</p> <p>10 Q It's a pretty well-recognized and accepted</p> <p>11 authority on gynecologic pathology; isn't it?</p> <p>12 A Well, it's one among many.</p> <p>13 Q Going back to the retrograde menstruation</p> <p>14 process we were talking about at the break, what's the</p> <p>15 biologic mechanism that causes this reverse upstream</p> <p>16 menstrual flow?</p> <p>17 A I don't know that anyone knows.</p> <p>18 Q Well, have you ever observed that process</p> <p>19 taking place?</p> <p>20 A Observed it? You mean like with a laparoscope</p> <p>21 and watched the blood flow? No, I haven't.</p> <p>22 Q Have you observed any evidence of that process</p> <p>23 taking place with the exception of the endometrial</p> <p>24 tissue being implanted on the ovary?</p> <p>25 A Please clarify. Rephrase that question.</p>	<p style="text-align: right;">Page 121</p> <p>1 BY MR. DEARING:</p> <p>2 Q How does -- how do endometrial cells implanted</p> <p>3 on the surface of the ovary cause endometrioid</p> <p>4 carcinoma?</p> <p>5 A Well, there's some interesting studies showing</p> <p>6 that, when you look at the endometrium of women with</p> <p>7 endometriosis -- so I'm saying the endometrium, within</p> <p>8 the lining of uterus -- and compare that to women who</p> <p>9 don't have endometriosis, there are certain molecular</p> <p>10 changes in the women with endometriosis -- in the</p> <p>11 lining of the uterus, in the endomet- -- that are</p> <p>12 different than the women who don't have endometriosis,</p> <p>13 suggesting that there's something different about that</p> <p>14 endometrium in women with endometriosis that leads to</p> <p>15 the development of endometriosis compared to other</p> <p>16 women who may also have retrograde menstruation but who</p> <p>17 don't develop endometriosis.</p> <p>18 Q Right. But what mechanism takes place to turn</p> <p>19 a displaced endometrial cell on the surface of the</p> <p>20 ovary in an endometrioid carcinoma?</p> <p>21 A Oh. Well, there's certain molecular genetic</p> <p>22 alterations that occur.</p> <p>23 Q Do they occur once they get to the ovary, or</p> <p>24 do they occur on the way to the ovary, or do they occur</p> <p>25 in the endometrium?</p>

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<p style="text-align: right;">Page 122</p> <p>1 A Well, that's what I was getting to just a</p> <p>2 moment ago. Some of those changes may already be</p> <p>3 present in the endometrium. So that would explain why</p> <p>4 some women -- women -- two women have retrograde</p> <p>5 menstruation; one gets endometriosis and the other one</p> <p>6 doesn't, because of those changes already present.</p> <p>7 Q Have you witnessed any of those cell changes</p> <p>8 in any kind of laboratory study or experiment?</p> <p>9 MS. AHERN: Objection. Form.</p> <p>10 THE WITNESS: Again, could you please rephrase what</p> <p>11 you mean by that.</p> <p>12 BY MR. DEARING:</p> <p>13 Q Well, let's say endometrial cells that don't</p> <p>14 already have some carcinogenic process taking place --</p> <p>15 A Okay.</p> <p>16 Q -- get -- you know, get free from the</p> <p>17 endometrium, go through the fallopian tubes, implant on</p> <p>18 the ovary.</p> <p>19 Are those cells capable of turning into</p> <p>20 endometrioid carcinoma?</p> <p>21 A Well, the -- based on that study -- there are</p> <p>22 a couple studies now -- it apparently doesn't occur.</p> <p>23 Or that's the suggestion, that it only occurs in women</p> <p>24 who have this genetic alteration to begin with.</p> <p>25 Because, otherwise, as we said, women -- many -- not</p>	<p style="text-align: right;">Page 124</p> <p>1 fimbriated ends of the tubes and the ovaries; is that a</p> <p>2 fair statement?</p> <p>3 MS. AHERN: Objection. Form.</p> <p>4 THE WITNESS: Well, I didn't say anything about</p> <p>5 other than blood and endometrial products that are in</p> <p>6 retrograde menstruation, and those are -- tend to be</p> <p>7 associated to a greater extent with clear cell and</p> <p>8 endometrioid carcinoma rather than high-grade serous</p> <p>9 carcinoma.</p> <p>10 BY MR. DEARING:</p> <p>11 Q Right. Were you taking exception to something</p> <p>12 I said in that statement?</p> <p>13 A Yes.</p> <p>14 Q Did I --</p> <p>15 A Well, do you want to repeat the statement --</p> <p>16 Q Sure.</p> <p>17 A -- and I'll point out where I'm differing.</p> <p>18 Q The statement is, if you ligate or close the</p> <p>19 fallopian tubes, endometrial material and potential</p> <p>20 environmental carcinogens are blocked. They cannot --</p> <p>21 A Stop. That's where I was disagreeing. "And</p> <p>22 potential environmental carcinogens," I didn't agree</p> <p>23 with that. I agreed with the blood but not with that</p> <p>24 part.</p> <p>25 Q What about environmental carcinogen -- what</p>
<p style="text-align: right;">Page 123</p> <p>1 many -- more normal women can have retrograde</p> <p>2 menstruation and don't get endometriosis.</p> <p>3 Q And using this diagram again, we were talking</p> <p>4 about tubal ligation.</p> <p>5 A Uh-huh.</p> <p>6 Q Where do tubal ligations typically take place</p> <p>7 surgically on the fallopian tube? Just anatomically,</p> <p>8 are they --</p> <p>9 A Yeah.</p> <p>10 Q -- on the distal end, or is it closer to</p> <p>11 the -- close to the uterus or where -- where are they</p> <p>12 usually ligated?</p> <p>13 A It can vary depending on when these are done,</p> <p>14 for example, laparoscopically, where the surgeon finds</p> <p>15 a good place to pick up with his forceps some fallopian</p> <p>16 tube to tie it off. So sometimes it's in the middle.</p> <p>17 Sometimes it's more distally. It's more often in the</p> <p>18 middle. That's what people aim for, rather than in the</p> <p>19 proximal end, which would be the end closer to the</p> <p>20 uterus.</p> <p>21 Q And the reason that tubal ligations reduce a</p> <p>22 woman's risk of ovarian cancer is because, if you</p> <p>23 ligate or close these tubes, endometrial material and</p> <p>24 potential environmental carcinogens are blocked and</p> <p>25 cannot pass through the fallopian tubes and reach the</p>	<p style="text-align: right;">Page 125</p> <p>1 about that statement do you disagree with?</p> <p>2 A Well, I don't know that environmental</p> <p>3 carcinogens have ever been demonstrated to go in</p> <p>4 retrograde menstruation.</p> <p>5 Q Is that one of those situations where it's not</p> <p>6 biologically plausible to you that tubal ligations</p> <p>7 would reduce potential for environmental carcinogens to</p> <p>8 reach ovaries because you haven't seen it?</p> <p>9 MS. AHERN: Objection. Form.</p> <p>10 THE WITNESS: I think it's speculation because I</p> <p>11 don't think there's been evidence produced to</p> <p>12 demonstrate that there are other environmental</p> <p>13 carcinogens or whatever that are coming into the</p> <p>14 uterus.</p> <p>15 BY MR. DEARING:</p> <p>16 Q Doctor, this is your sixth edition of</p> <p>17 Blaustein's.</p> <p>18 A Ah, yes.</p> <p>19 Q You recognize it?</p> <p>20 A Yes.</p> <p>21 Q This is the most current edition; right?</p> <p>22 A Currently, that's right.</p> <p>23 Q I'm sorry. I don't have six copies of this.</p> <p>24 It's very heavy. But I do want to ask you about</p> <p>25 something.</p>



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<p style="text-align: right;">Page 126</p> <p>1 A Okay.</p> <p>2 Q So I'm referring to Chapter 14 of this book.</p> <p>3 And Chapter 14 is entitled "Surface Epithelial Tumors</p> <p>4 of the Ovary."</p> <p>5 You're familiar with this chapter; right?</p> <p>6 A Yes.</p> <p>7 Q And you're one of the authors of this chapter;</p> <p>8 right?</p> <p>9 A Yes.</p> <p>10 Q On page 681 of this chapter, you're</p> <p>11 discussing, for context, etiology and risk factors for</p> <p>12 ovarian cancer; right?</p> <p>13 A Well, I'll have to see. I can't read it from</p> <p>14 there.</p> <p>15 Q Well -- all right. So this is the title page,</p> <p>16 "Surface Epithelial Tumors of the Ovary."</p> <p>17 And you see the first section says</p> <p>18 "Epidemiology"; right?</p> <p>19 A Well, I can't. Maybe you can magnify it</p> <p>20 greater.</p> <p>21 Q Maybe.</p> <p>22 A I can see "Surface Epithelial," but I can't</p> <p>23 see the subheadings.</p> <p>24 MS. AHERN: I think part of it is the glare from</p> <p>25 the lighting is making it a little hard to read.</p>	<p style="text-align: right;">Page 128</p> <p>1 tubal ligation prevent the introduction</p> <p>2 of a variety of potential environmental</p> <p>3 carcinogens from entering the peritoneal</p> <p>4 cavity and thereby coming into contact</p> <p>5 with tubal and ovarian tissue."</p> <p>6 That's where I got that statement from.</p> <p>7 So are you now saying you disagree with your</p> <p>8 statements in this textbook with regard to</p> <p>9 environmental carcinogens?</p> <p>10 A Well, you have to understand textbooks. You</p> <p>11 basically cite what's out there. And what we're</p> <p>12 stating there is what some people have allegedly</p> <p>13 reported, so that we're trying to be complete.</p> <p>14 Q No, Doctor, that's not what somebody alleged</p> <p>15 in a report. That's the predominant theory. That's</p> <p>16 why that's in the textbook.</p> <p>17 You're not saying this is what a few people</p> <p>18 say. You're saying this because this is the</p> <p>19 predominant theory; right?</p> <p>20 A I didn't say --</p> <p>21 MS. AHERN: Objection. Argumentative.</p> <p>22 THE WITNESS: I didn't.</p> <p>23 MS. AHERN: Object to the form.</p> <p>24 THE WITNESS: Sorry.</p> <p>25 I didn't say anything about the predominance.</p>
<p style="text-align: right;">Page 127</p> <p>1 THE WITNESS: That's better.</p> <p>2 BY MR. DEARING:</p> <p>3 Q Okay. It'll be easy for you to read along</p> <p>4 with me, but...</p> <p>5 So this is the chapter on surface epithelial</p> <p>6 tumors of the ovary.</p> <p>7 A Correct.</p> <p>8 Q And then the first few pages discusses</p> <p>9 epidemiology; right?</p> <p>10 A Yes, it does.</p> <p>11 Q Okay. And then over here, one of the first</p> <p>12 sections it talks about is etiology and risk factors.</p> <p>13 See that at the bottom there?</p> <p>14 A Yes.</p> <p>15 Q Okay. Then I'm going -- I'm only showing you</p> <p>16 that to show you that's the section that we're in.</p> <p>17 A Okay.</p> <p>18 Q I'm flipping over to the next page, which is</p> <p>19 681. And at the bottom of 681, you see it says</p> <p>20 "Reproductive Factors."</p> <p>21 And then this is the part I want to read to</p> <p>22 you. So we're talking about etiology and risk factors</p> <p>23 and, within that heading, reproductive factors. And</p> <p>24 you say:</p> <p>25 "In addition, hysterectomy and</p>	<p style="text-align: right;">Page 129</p> <p>1 I said it's a view that's out there and that's</p> <p>2 reported. I didn't say anything about -- that it's the</p> <p>3 predominant.</p> <p>4 BY MR. DEARING:</p> <p>5 Q It wouldn't be in this textbook and written</p> <p>6 that way if it wasn't biologically plausible, would it</p> <p>7 be?</p> <p>8 MS. AHERN: Objection. Form.</p> <p>9 THE WITNESS: I'm not getting into biologically</p> <p>10 plausible. We've already discussed that. It's been</p> <p>11 described by some people. So in fairness to those</p> <p>12 other reports, we've included it in the chapter.</p> <p>13 BY MR. DEARING:</p> <p>14 Q But you didn't even cite to anybody else.</p> <p>15 There's no cite there.</p> <p>16 A It's kind of a general statement.</p> <p>17 Q So it's your testimony that you put that</p> <p>18 statement that tubal ligations and hysterectomies offer</p> <p>19 protective effect against environmental carcinogens</p> <p>20 because a few scientists have said that?</p> <p>21 MS. AHERN: Objection. Form. Argumentative.</p> <p>22 THE WITNESS: I didn't say "a few" or whatever. I</p> <p>23 just said it's out there. So I -- we mentioned it. We</p> <p>24 included it.</p> <p>25 ///</p>

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<p style="text-align: right;">Page 130</p> <p>1 BY MR. DEARING:</p> <p>2 Q Do you agree with me that, with regard to this</p> <p>3 statement and the protective effect of hysterectomies</p> <p>4 and tubal ligations against the introduction of</p> <p>5 environmental carcinogens, that there's no qualifying</p> <p>6 language associated with this statement like "I don't</p> <p>7 really believe this" or "This is an outlier-type</p> <p>8 opinion"? There's nothing like that in that statement,</p> <p>9 is there?</p> <p>10 A That's true.</p> <p>11 Q And this textbook, which you just said is for</p> <p>12 doctors, medical students, scientists, people that want</p> <p>13 to know, if they wanted to know what's -- you know,</p> <p>14 does hysterectomy and tubal ligation offer protective</p> <p>15 effect against ovarian cancer, they would look to your</p> <p>16 textbook.</p> <p>17 And all it says is it does offer protective</p> <p>18 effect against environmental -- potential environmental</p> <p>19 carcinogens; right?</p> <p>20 MS. AHERN: Objection. Form.</p> <p>21 THE WITNESS: It's --</p> <p>22 BY MR. DEARING:</p> <p>23 Q In other words, there's no alternative view</p> <p>24 stated there, is there?</p> <p>25 MS. AHERN: Objection. Form.</p>	<p style="text-align: right;">Page 132</p> <p>1 see if you can make it --</p> <p>2 Q Sure. There you go.</p> <p>3 A Yeah, that's what it says.</p> <p>4 Q Okay. I wasn't trying to trick you.</p> <p>5 A Well, I just want to be sure if it's correctly</p> <p>6 stated.</p> <p>7 I have to make a minor equipment change here.</p> <p>8 Okay.</p> <p>9 Q This textbook was published in 2011; right?</p> <p>10 A That's correct.</p> <p>11 Q So it was published before you were retained</p> <p>12 as an expert by Johnson &amp; Johnson; right?</p> <p>13 A Correct.</p> <p>14 Q Do you agree that if talc can reach the</p> <p>15 uterus, then it could reach the ovaries?</p> <p>16 A I don't --</p> <p>17 MS. AHERN: Objection. Form.</p> <p>18 THE WITNESS: I don't agree that talc can reach the</p> <p>19 uterus.</p> <p>20 BY MR. DEARING:</p> <p>21 Q Right. I'm just asking you hypothetically, if</p> <p>22 talc could reach the uterus, then do you think it could</p> <p>23 also reach the ovaries, either through retrograde</p> <p>24 menstruation or some other process?</p> <p>25 MS. AHERN: Objection. Form.</p>
<p style="text-align: right;">Page 131</p> <p>1 THE WITNESS: What's stated there is what's stated</p> <p>2 there, yes.</p> <p>3 BY MR. DEARING:</p> <p>4 Q Okay. While I have the book open, I asked you</p> <p>5 a specific question about whether you agreed that</p> <p>6 retrograde menstruation is a common physiologic process</p> <p>7 that occurs in 90 percent of menstruating women with</p> <p>8 normal unoccluded fallopian tubes, and you said you</p> <p>9 think that it's a lot of women or it's a majority.</p> <p>10 A Yeah, it is pretty high.</p> <p>11 Q Well, would it surprise you that that</p> <p>12 90 percent came from your textbook?</p> <p>13 A Well, I'd like to see it.</p> <p>14 Q Okay. On page 642 where you're describing</p> <p>15 endometriosis, see there, and usual sites?</p> <p>16 A I see that.</p> <p>17 Q The next column over where I have the blue</p> <p>18 marker, it says:</p> <p>19 "Retrograde menstruation through</p> <p>20 the fallopian tubes is a common</p> <p>21 physiologic process occurring in</p> <p>22 90 percent of menstruating women with</p> <p>23 patent tubes."</p> <p>24 Do you agreed with that statement?</p> <p>25 A Well, can I -- I can't read that. I want to</p>	<p style="text-align: right;">Page 133</p> <p>1 THE WITNESS: Again, there's no data. I have no --</p> <p>2 no data, so I can't say that it could.</p> <p>3 BY MR. DEARING:</p> <p>4 Q Well, I'm asking you as a 40-year experienced</p> <p>5 gynecologic pathologist. Okay. Relying on all the</p> <p>6 experience that you've -- relying on all of your</p> <p>7 experience, do you have an opinion either way whether,</p> <p>8 if talc could reach the uterus, then it could probably</p> <p>9 reach the ovaries?</p> <p>10 A Pure speculation. I can't comment on that.</p> <p>11 Q Well, you're an expert. You are allowed to</p> <p>12 speculate.</p> <p>13 A Doesn't matter if I'm an expert. It's</p> <p>14 speculation.</p> <p>15 Q Okay. So you --</p> <p>16 A It's meaningless.</p> <p>17 Q So you don't have an opinion either way?</p> <p>18 A I told you I don't think it could reach the</p> <p>19 uterus, and I don't -- and, therefore, I don't think it</p> <p>20 can go any further. It can't get to the uterus.</p> <p>21 Q If it was implanted in the uterus, do you</p> <p>22 think could reach the ovaries?</p> <p>23 MS. AHERN: Objection. Form.</p> <p>24 THE WITNESS: Again, show me a study where they've</p> <p>25 done that, and then I can, you know, intelligently</p>

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<p style="text-align: right;">Page 134</p> <p>1 discuss it.</p> <p>2 BY MR. DEARING:</p> <p>3 Q So without seeing a study, you have no opinion</p> <p>4 either way whether talc could move from the uterus to</p> <p>5 the ovary?</p> <p>6 A That's not science. It's just speculation.</p> <p>7 Q Okay. Is retrograde menstruation one of those</p> <p>8 biologically plausible ideas that you do believe exists</p> <p>9 even though you haven't seen it take place?</p> <p>10 MS. AHERN: Objection. Form.</p> <p>11 THE WITNESS: Wait. I'm sorry.</p> <p>12 BY MR. DEARING:</p> <p>13 Q You have testified you've never seen</p> <p>14 retrograde menstruation take place, but you do say that</p> <p>15 it's biologically plausible.</p> <p>16 A Well, I said, in fact, that I've seen, in</p> <p>17 microscopic sections of the fallopian tube, parts of</p> <p>18 endometrial tissue and blood in the lumen of the</p> <p>19 fallopian tube. So, yes, I think it can occur.</p> <p>20 Q I can't remember if you answered this. If you</p> <p>21 did, I apologize.</p> <p>22 You've said retrograde menstruation occurs</p> <p>23 during the regular menstrual cycle of a woman. And I</p> <p>24 said does that mean you're saying it flows both ways at</p> <p>25 the same time, and you said yes.</p>	<p style="text-align: right;">Page 136</p> <p>1 THE WITNESS: Well, I should say that, at times,</p> <p>2 there can be a lesion that comes from another site that</p> <p>3 mimics serous tubal intraepithelial carcinoma, so you</p> <p>4 have to be very careful when you draw that conclusion.</p> <p>5 BY MR. DEARING:</p> <p>6 Q Sir, that's not the question I'm asking.</p> <p>7 A Oh, okay.</p> <p>8 Q Can a trained pathologist tell by looking at a</p> <p>9 tumor whether it came from the fallopian tube or</p> <p>10 whether it originated at the ovaries?</p> <p>11 A Well, you can't do it simply on H&amp;E analysis.</p> <p>12 You really require molecular analysis to demonstrate</p> <p>13 that it's cloned, that the same genetic alterations</p> <p>14 that are present in the STIC are present in the -- in</p> <p>15 the corresponding ovarian cancer.</p> <p>16 Q So a surgical pathologist, for example,</p> <p>17 looking at a surgical specimen from an oophorectomy</p> <p>18 that's been diagnosed, at least before surgery, as</p> <p>19 ovarian cancer can't tell if that carcinoma originated</p> <p>20 from the ovary or the fallopian tube by looking at the</p> <p>21 tumor; right?</p> <p>22 MS. AHERN: Objection. Form.</p> <p>23 THE WITNESS: Just looking at the H&amp;E, based on the</p> <p>24 studies that have been published, I think it would be</p> <p>25 reasonable to suspect that that's where it came from.</p>
<p style="text-align: right;">Page 135</p> <p>1 Do you know what specifically causes it to</p> <p>2 flow upstream, you know, towards the fallopian tube?</p> <p>3 A I have no idea. I don't think anyone has.</p> <p>4 Q In your report, on page 6, under the section</p> <p>5 "Precursor Lesions" --</p> <p>6 A Yes.</p> <p>7 Q -- you state:</p> <p>8 "Our understanding of the</p> <p>9 pathogenesis of ovarian cancer has</p> <p>10 advanced in the last few years with the</p> <p>11 recognition that many high-grade serous</p> <p>12 carcinomas developed from a precursor</p> <p>13 lesion in the fallopian tube designated</p> <p>14 serous tubal intraepithelial carcinomas</p> <p>15 or STIC."</p> <p>16 Did I read that right?</p> <p>17 A Yes, that's correctly stated as it's written,</p> <p>18 yes.</p> <p>19 Q Do you believe that most high-grade serous</p> <p>20 ovarian cancers derive from the fallopian tube?</p> <p>21 A I do.</p> <p>22 Q Can a trained pathologist tell if a cancer</p> <p>23 derived from the fallopian tube by looking at it under</p> <p>24 a microscope?</p> <p>25 MS. AHERN: Objection. Form.</p>	<p style="text-align: right;">Page 137</p> <p>1 BY MR. DEARING:</p> <p>2 Q But there's no characteristic about the tumor</p> <p>3 that tells you that; right? There's nothing you can</p> <p>4 see under a microscope where you could say, "Oh, that</p> <p>5 came from the fallopian tube versus ovarian primary"?</p> <p>6 MS. AHERN: Object.</p> <p>7 THE WITNESS: That's correct.</p> <p>8 BY MR. DEARING:</p> <p>9 Q And when you're using the term "precursor</p> <p>10 lesion" in your report, what do you mean by that? How</p> <p>11 do you define "precursor lesion"?</p> <p>12 A Well, it's a lesion that precedes the</p> <p>13 development of, in this case, invasive carcinoma.</p> <p>14 Because a STIC is a cancer in situ, if you will, but</p> <p>15 there are other lesions in the p53 signatures which are</p> <p>16 benign that appear to precede the development of STICs.</p> <p>17 Q And you don't believe type 1 tumors originate</p> <p>18 in the fallopian tube, do you?</p> <p>19 A Well, we think possibly that some low-grade</p> <p>20 serous carcinomas, which are type 1 tumors, may well</p> <p>21 arise from fallopian tube, but in a different</p> <p>22 mechanism.</p> <p>23 Q Can you give me an example of a fallopian tube</p> <p>24 precursor lesion that may be a precursor for any type</p> <p>25 of ovarian cancer?</p>

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<p style="text-align: right;">Page 138</p> <p>1 A STIC, or p53 signature.</p> <p>2 Q So you're saying it is a -- that type 2 tumors</p> <p>3 start out as serous tubal intraepithelial carcinomas in</p> <p>4 the fallopian tube, and then somehow migrate from the</p> <p>5 fallopian tube to the ovaries?</p> <p>6 MS. AHERN: Objection. Form.</p> <p>7 THE WITNESS: Yes. That's correct.</p> <p>8 BY MR. DEARING:</p> <p>9 Q What mechanism propels it through the</p> <p>10 fallopian tube to make it implant on the ovary?</p> <p>11 A Well, there may be a number of ways. One way</p> <p>12 is that these STIC cells have this cohesiveness, so</p> <p>13 that they are breaking off and they can fall into the</p> <p>14 fallopian tube and they could migrate up that way, or</p> <p>15 they might even be -- even though they are noninvasive,</p> <p>16 there may be a way, it has been suggested -- I'm not</p> <p>17 sure it is well documented -- it somehow may get into</p> <p>18 lymphatics and get into the ovary that way.</p> <p>19 Q What are some of the causes of fallopian tube</p> <p>20 precursor lesions?</p> <p>21 MS. AHERN: Objection. Form.</p> <p>22 THE WITNESS: We don't know what they are.</p> <p>23 BY MR. DEARING:</p> <p>24 Q Could environmental carcinogens be a potential</p> <p>25 cause of a tubal precursor lesion?</p>	<p style="text-align: right;">Page 140</p> <p>1 MS. AHERN: Objection.</p> <p>2 THE WITNESS: Please rephrase the question.</p> <p>3 MR. DEARING: Sure.</p> <p>4 BY MR. DEARING:</p> <p>5 Q You obviously think that this precursor tubal</p> <p>6 lesion idea that is a precursor lesion for ovarian</p> <p>7 cancers --</p> <p>8 A For high-grade serous ovarian cancers.</p> <p>9 Q And some low-grade, you said?</p> <p>10 A No, no. It's a different mechanism.</p> <p>11 Q Let's stick with high-grade serous. That's</p> <p>12 the majority of cancers anyway, isn't it?</p> <p>13 A Yes.</p> <p>14 Q So are you saying that these tubal lesions</p> <p>15 are -- are you saying it's biologically plausible that</p> <p>16 these tubal lesions are precursor lesions to high-grade</p> <p>17 serous carcinomas where they're starting in the tube</p> <p>18 and implanting in the ovary?</p> <p>19 A That's the mechanism we think is at play, yes.</p> <p>20 Q And you believe that's a biologically</p> <p>21 plausible explanation for that process even though you</p> <p>22 don't know what's causing the tubal lesions; right?</p> <p>23 MS. AHERN: Objection. Form.</p> <p>24 THE WITNESS: We're saying that we don't know the</p> <p>25 cause of STIC, but we know that it has mutations and</p>
<p style="text-align: right;">Page 139</p> <p>1 A Well, we haven't made that finding yet.</p> <p>2 Q If talc could reach the fallopian tubes, could</p> <p>3 talc serve as a catalyst for a precursor lesion that</p> <p>4 would create a STIC that might lead to an ovarian</p> <p>5 cancer?</p> <p>6 MS. AHERN: Objection. Form.</p> <p>7 THE WITNESS: Well, based on what we've seen with</p> <p>8 talc in other locations, such as when it's used in</p> <p>9 pleurodesis -- long-term studies have not shown the</p> <p>10 development of carcinoma -- I don't think it would</p> <p>11 cause ovarian cancer.</p> <p>12 BY MR. DEARING:</p> <p>13 Q Well, if -- if foreign bodies aren't causing</p> <p>14 tubal precursor lesions, can you give me an example of</p> <p>15 anything that does? Anything that's not bacterial.</p> <p>16 MS. AHERN: Objection. Form.</p> <p>17 THE WITNESS: It's an area we just don't know.</p> <p>18 Something causes a p53 mutation -- we don't know what</p> <p>19 it does, what it is -- and that starts the ball</p> <p>20 rolling.</p> <p>21 BY MR. DEARING:</p> <p>22 Q And you think that's a biologically plausible</p> <p>23 explanation for the carcinogenesis of some ovarian</p> <p>24 cancers even though you've never seen it?</p> <p>25 A May I please --</p>	<p style="text-align: right;">Page 141</p> <p>1 morphologic changes that are exactly the same as those</p> <p>2 in high-grade serous carcinomas. So we're able to make</p> <p>3 that jump, but we don't know -- we'd love to know what</p> <p>4 the cause of a STIC is. Prevention is, to me, the only</p> <p>5 way we're going to make headway and, really, an impact</p> <p>6 on preventing the development of that. But we have no</p> <p>7 idea what it is that we need to prevent at this point.</p> <p>8 BY MR. DEARING:</p> <p>9 Q Could tubal exposure to exogenous or</p> <p>10 environmental materials cause tubal precursor lesions?</p> <p>11 MS. AHERN: Objection. Form.</p> <p>12 THE WITNESS: We don't know.</p> <p>13 BY MR. DEARING:</p> <p>14 Q Well, are these serous tubal intraepithelial</p> <p>15 carcinomas -- do they derive from inflammation? Or do</p> <p>16 you not know that either?</p> <p>17 A No, I see -- I've looked at a lot of these,</p> <p>18 and I've never seen inflammation of any type associated</p> <p>19 with STICs.</p> <p>20 Q Are you aware of any reason why a potential</p> <p>21 environmental carcinogen could not be a cause or a</p> <p>22 precipitating exposure of a STIC?</p> <p>23 MS. AHERN: Objection. Form.</p> <p>24 THE WITNESS: Please repeat the question.</p> <p>25 ///</p>

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<p style="text-align: right;">Page 142</p> <p>1 BY MR. DEARING:</p> <p>2 Q So you said you don't know, or we don't know,</p> <p>3 whether environmental materials are causing these</p> <p>4 STICs.</p> <p>5 A Right.</p> <p>6 Q Is there any particular reason why it could</p> <p>7 not be an environmental material causing these STICs?</p> <p>8 MS. AHERN: Objection. Form.</p> <p>9 THE WITNESS: It is a negative question. I mean,</p> <p>10 we don't know. It doesn't tell me anything. I still</p> <p>11 can't really quite figure out what you're driving at.</p> <p>12 BY MR. DEARING:</p> <p>13 Q Well, let me ask it in the positive form of</p> <p>14 that question. Is it possible that some of those</p> <p>15 precursor lesions are caused by environmental</p> <p>16 materials?</p> <p>17 MS. AHERN: Objection. Form.</p> <p>18 THE WITNESS: We need to see the data.</p> <p>19 BY MR. DEARING:</p> <p>20 Q So you can't say yes or no to that question?</p> <p>21 A That's right. It's not known.</p> <p>22 Q Well, you would agree that it is well known</p> <p>23 that tubal epithelial inflammation can stimulate</p> <p>24 proliferation of the epithelium and instigate</p> <p>25 pathogenesis of tubal hyperplasia; right?</p>	<p style="text-align: right;">Page 144</p> <p>1 in the pathogenesis of papillary tubal hyperplasia and</p> <p>2 endosalpingiosis."</p> <p>3 A Sounds like it's taken out of my paper.</p> <p>4 Q It is.</p> <p>5 A Our paper. But, again, we talked about it</p> <p>6 earlier. That refers specifically to serous borderline</p> <p>7 tumors, which is a precursor, if you will, of low-grade</p> <p>8 serous carcinoma, not high-grade serous carcinoma.</p> <p>9 They're different. They're totally different.</p> <p>10 Q Okay. Well, let's talk about low-grade serous</p> <p>11 carcinomas and borderline tumors.</p> <p>12 A Okay.</p> <p>13 Q Are you agreeing with me, then, with regard to</p> <p>14 those tumors that an inflammatory process within the</p> <p>15 fallopian tube is what stimulates the proliferation of</p> <p>16 the tubal epithelium?</p> <p>17 A That's our hypothesis. That is to say that</p> <p>18 inflammation virtually -- basically meaning pelvic</p> <p>19 inflammatory disease due to sexually transmitted</p> <p>20 disease -- we haven't demonstrated that, but that's our</p> <p>21 thinking. So it's a hypothesis that we've put out</p> <p>22 because inflammation of that sort can produce</p> <p>23 proliferation of tubal epithelium.</p> <p>24 Proliferation of tubal epithelium in and of</p> <p>25 itself doesn't mean it's going to go on to the next</p>
<p style="text-align: right;">Page 143</p> <p>1 MS. AHERN: Objection. Form.</p> <p>2 THE WITNESS: That's correct. That's in our paper.</p> <p>3 BY MR. DEARING:</p> <p>4 Q So inflammation can play a role in the</p> <p>5 development of some precursor lesions within the</p> <p>6 fallopian tube.</p> <p>7 MS. AHERN: Objection. Form.</p> <p>8 THE WITNESS: Proliferation isn't the precursor</p> <p>9 lesion. Proliferation can occur in completely benign</p> <p>10 conditions. It has nothing to do with cancer.</p> <p>11 BY MR. DEARING:</p> <p>12 Q Right. But it's the epithelial inflammation</p> <p>13 that's creating the proliferation of the epithelium;</p> <p>14 right?</p> <p>15 MS. AHERN: Objection. Form.</p> <p>16 THE WITNESS: The epithelial -- the inflammation</p> <p>17 that we describe in our paper on papillary tubal</p> <p>18 hyperplasia, I think it's important to point out, is</p> <p>19 due to pelvic inflammatory disease, not due to talc</p> <p>20 exposure.</p> <p>21 BY MR. DEARING:</p> <p>22 Q Tell me if you agree with this sentence: "It</p> <p>23 is well known that an inflammation may stimulate</p> <p>24 proliferation of tubal epithelium; and, therefore, it</p> <p>25 is plausible that chronic salpingitis may play a role</p>	<p style="text-align: right;">Page 145</p> <p>1 step, a borderline tumor. You may have tubal</p> <p>2 proliferation; nothing else happens.</p> <p>3 Q Do you have any opinion as to what may be</p> <p>4 causing inflammation that may stimulate proliferation</p> <p>5 of tubal epithelium?</p> <p>6 A As I said, we're thinking maybe pelvic</p> <p>7 inflammatory disease, chlamydia, gonorrhea, those kinds</p> <p>8 of sexually transmitted diseases may account for that.</p> <p>9 Q So when you say in your report, "I have</p> <p>10 participated in a number of studies assessing the</p> <p>11 characteristics of" --</p> <p>12 A Where are we talking about now?</p> <p>13 Q I'm sorry. Page 18.</p> <p>14 A Okay. I'm at 18.</p> <p>15 Q It's near the top.</p> <p>16 A Okay.</p> <p>17 Q It's right in the middle of the first</p> <p>18 paragraph.</p> <p>19 A Okay. "I have participated." Go ahead, yeah.</p> <p>20 Q "I have participated in a number</p> <p>21 of studies assessing the characteristics</p> <p>22 of serous tubal intraepithelial</p> <p>23 carcinomas and have not found them to be</p> <p>24 associated with inflammation."</p> <p>25 That statement is not true if you substituted</p>



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<p style="text-align: right;">Page 146</p> <p>1 STIC for low-grade serous carcinomas; right?</p> <p>2 MS. AHERN: Objection. Form.</p> <p>3 THE WITNESS: STICs are precursors of high-grade</p> <p>4 serous carcinoma --</p> <p>5 BY MR. DEARING:</p> <p>6 Q I know.</p> <p>7 A -- not low-grade.</p> <p>8 Q Right. But my point is, even though you say</p> <p>9 you have not seen STICs associated with inflammation,</p> <p>10 you have seen low-grade serous carcinomas associated</p> <p>11 with inflammation; right? That's what we were just</p> <p>12 talking about.</p> <p>13 A We've seen --</p> <p>14 MS. AHERN: Objection. Form.</p> <p>15 THE WITNESS: Sorry.</p> <p>16 We have seen inflammation associated with</p> <p>17 papillary tubal hyperplasia. That's what that paper</p> <p>18 shows.</p> <p>19 BY MR. DEARING:</p> <p>20 Q Well, papillary tubal hyperplasia can be a</p> <p>21 precursor lesion to ovarian cancer, can't it?</p> <p>22 MS. AHERN: Objection. Form.</p> <p>23 THE WITNESS: Can be a precursor of borderline</p> <p>24 tumors, which can then be a precursor -- not all of</p> <p>25 them. Very few of them progress to low-grade serous</p>	<p style="text-align: right;">Page 148</p> <p>1 MS. AHERN: Objection. Form.</p> <p>2 THE WITNESS: We're again talking about ovarian</p> <p>3 high-grade serous carcinomas.</p> <p>4 BY MR. DEARING:</p> <p>5 Q Yes.</p> <p>6 A Yes, I think that happens.</p> <p>7 Q Okay. So one of the things you said</p> <p>8 previously was you don't believe talc can cause ovarian</p> <p>9 cancer because you've seen no evidence that talc causes</p> <p>10 foreign-body granulomatous reactions in gynecologic</p> <p>11 tissue; right?</p> <p>12 MS. AHERN: Objection. Mischaracterizes testimony.</p> <p>13 BY MR. DEARING:</p> <p>14 Q Does that mischaracterize your testimony?</p> <p>15 A Repeat what you just said.</p> <p>16 Q Sure.</p> <p>17 You said you do not believe that talcum powder</p> <p>18 exposure can cause ovarian cancer of any sort because</p> <p>19 you have not seen evidence of a foreign-body reaction,</p> <p>20 granulomatous reaction, to talc in gynecologic tissue?</p> <p>21 MS. AHERN: Same objection. Mischaracterizes</p> <p>22 testimony.</p> <p>23 BY MR. DEARING:</p> <p>24 Q What did I get wrong?</p> <p>25 A Yes. Okay.</p>
<p style="text-align: right;">Page 147</p> <p>1 carcinoma. So it could be, but many of them don't.</p> <p>2 BY MR. DEARING:</p> <p>3 Q Well, and, of course, some borderline serous</p> <p>4 tumors progress into invasive serous tumors, don't</p> <p>5 they?</p> <p>6 A They progress to invasive low-grade serous</p> <p>7 carcinomas, some of them.</p> <p>8 Q And they can also implant in other organs,</p> <p>9 can't they?</p> <p>10 A Yes, they can.</p> <p>11 Q Incidentally, this paper that we're talking</p> <p>12 about, the papillary tubal hyperplasia paper that you</p> <p>13 wrote, it also includes some epidemiology information,</p> <p>14 doesn't it?</p> <p>15 MS. AHERN: Objection. Form.</p> <p>16 THE WITNESS: You'll have to tell me -- show me</p> <p>17 exactly what you are talking about.</p> <p>18 MR. DEARING: Actually, you know what? I'm not.</p> <p>19 Let's move on with this.</p> <p>20 BY MR. DEARING:</p> <p>21 Q Do you agree that ovarian cancer precursor</p> <p>22 lesions are rarely seen or observed because ovarian</p> <p>23 carcinomas typically present in advanced stage and</p> <p>24 those precursor lesions are obliterated or rendered</p> <p>25 unrecognizable by the cancer?</p>	<p style="text-align: right;">Page 149</p> <p>1 Q Is that your testimony?</p> <p>2 A Yes.</p> <p>3 Q Your attorney doesn't think so.</p> <p>4 MS. AHERN: The record will reflect --</p> <p>5 BY MR. DEARING:</p> <p>6 Q Did I say it right?</p> <p>7 MS. AHERN: -- what his testimony was earlier.</p> <p>8 THE WITNESS: You said the ovary.</p> <p>9 BY MR. DEARING:</p> <p>10 Q In fact, you said, "I don't even think it's</p> <p>11 biologically plausible because I've never seen it."</p> <p>12 Right? Remember that whole line of questions?</p> <p>13 A I've never seen talc, yeah, in association</p> <p>14 with precursor lesions or high-grade ovarian carcinoma.</p> <p>15 Q Right. What you said is you didn't believe</p> <p>16 talc could cause ovarian cancer because you haven't</p> <p>17 seen the foreign-body granulomatous response to talc</p> <p>18 that you would expect to see --</p> <p>19 MS. AHERN: Objection. Form.</p> <p>20 BY MR. DEARING:</p> <p>21 Q -- from talc exposure; right?</p> <p>22 MS. AHERN: Mischaracterizing testimony.</p> <p>23 THE WITNESS: I think we need to be clear that,</p> <p>24 even if we saw -- even if we saw talc in the case of</p> <p>25 ovarian cancer, it doesn't mean that it caused it.</p>

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<p style="text-align: right;">Page 150</p> <p>1 It's just like I said with the HSV, which all those 2 studies showed HSV and cervical cancer and it was 3 totally wrong. So the fact that you see it in there 4 doesn't mean it's causing them. 5 In fact, in order to have any kind of -- 6 you've got to focus on early lesions. Those are the 7 precursors. That's where the cancer starts, not in the 8 end product, which is cancer. You can see 9 inflammation, of course, all over the place in a 10 cancer. 11 BY MR. DEARING: 12 Q Right. I'm just trying to make sure that I 13 have this fine point of your testimony correct, and 14 that is, is it your opinion that talc cannot cause 15 ovarian cancer of any sort because you have seen no 16 evidence that talc elicits a foreign-body granulomatous 17 response in gynecologic tissue? 18 MS. AHERN: Objection. Mischaracterizes his 19 testimony. 20 THE WITNESS: We've seen talc does not cause 21 ovarian cancer. So one has nothing to do with the 22 other. 23 BY MR. DEARING: 24 Q Have you observed any precancerous lesions in 25 ovarian tissue?</p>	<p style="text-align: right;">Page 152</p> <p>1 obliterated or rendered unrecognizable by the cancer? 2 A Can be. 3 MS. AHERN: Objection. Form. 4 THE WITNESS: Can be. 5 BY MR. DEARING: 6 Q Can be what? 7 A Can be obliterated. Not in all cases. Most 8 of the cases you see it -- or many of the cases you see 9 it. Some cases you don't, so we've come to the -- 10 well, we've done a study to show that women who have 11 high-grade serous carcinoma, all stages, with STICs and 12 compare them to women, all -- this high-grade serous 13 carcinoma, all stages without STICs, we've analyzed the 14 molecular genetic features of those carcinomas. They 15 are no different between the ones with STICs and the 16 ones without STICs. Consequently, we think that some 17 of those cases in which you don't see evidence of the 18 STIC was due to overgrowth by the cancer. But a lot of 19 times, the STIC is evident. 20 BY MR. DEARING: 21 Q Do you agree that those precursor lesions are 22 rarely seen or observed? 23 MS. AHERN: Objection. Form. 24 BY MR. DEARING: 25 Q That's what the statement says, they are</p>
<p style="text-align: right;">Page 151</p> <p>1 A In ovarian tissue, precancerous lesions? Very 2 interesting question. We -- and I say "we," the 3 pathology community -- spent 40 years looking for 4 precursors in ovarian tissue and never found it. So 5 that's why the STIC was such a finding, was such a 6 surprise, and was such a revelation in terms of 7 elucidating the early lesions that could go on to the 8 development of high-grade serous carcinoma. 9 Q So have you seen precursor lesions in ovaries? 10 A No. 11 MS. AHERN: Objection. Form. 12 BY MR. DEARING: 13 Q Have you even precursor lesions that are 14 precancerous in fallopian tubes? 15 A That's what we are talking about. STICs, we 16 think, are precursors of invasive cancer. P53 17 signatures in the fallopian tube are precursors, in 18 some instances, of STICs. 19 Q And when you're observing the STICs, are you 20 observing them in the fallopian tube or in the ovary? 21 A In the fallopian tube. 22 Q So back to my statement. Do you agree that 23 ovarian cancer precursor lesions are rarely seen or 24 observed because ovarian carcinomas typically present 25 in advanced stage and those precursor lesions are</p>	<p style="text-align: right;">Page 153</p> <p>1 rarely seen or observed. Do you agree with that? 2 A What statement is this? 3 Q One I've read twice now. I can read it a 4 third time if you would like. 5 A Read it again, please. 6 Q Do you agree that ovarian cancer -- 7 A Can you show me where you reading from? 8 Q Yes. Do you agree that ovarian -- 9 A No, I want to see it. 10 Q Listen to it first. 11 Do you agree that ovarian cancer precursor 12 lesions are rarely seen or observed because ovarian 13 carcinomas typically present in advanced stage and 14 those precursor lesions are obliterated or rendered 15 unrecognizable by the cancer? 16 MS. AHERN: Objection. Form. 17 THE WITNESS: Okay. Not rarely. I would disagree 18 with "rarely." 19 BY MR. DEARING: 20 Q Rarely. Okay. 21 A Right. In other words, yeah, sometimes you 22 don't see them; many times you do see them. 23 Q Okay. Turning to page 685 of the same 24 Blaustein textbook you looked at earlier, I'm still in 25 Chapter 14, of which you were an author.</p>

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<p style="text-align: right;">Page 154</p> <p>1 MS. AHERN: Page -- I'm sorry -- 285?</p> <p>2 MR. DEARING: 685.</p> <p>3 MS. AHERN: 685. Thank you.</p> <p>4 MR. DEARING: I'll try to position this.</p> <p>5 MS. AHERN: What year is that edition?</p> <p>6 THE WITNESS: 2011, I think.</p> <p>7 MR. DEARING: It's the most current.</p> <p>8 THE WITNESS: You can see that.</p> <p>9 MS. AHERN: Okay. Thank you.</p> <p>10 BY MR. DEARING:</p> <p>11 Q It's under the subheading "Putative</p> <p>12 Histopathologic Precursor Lesions." And you write:</p> <p>13 "The study of precursors of ovarian</p> <p>14 carcinoma is difficult because the</p> <p>15 ovaries are not readily accessible for</p> <p>16 screening and ovarian carcinomas</p> <p>17 typically present in advanced stage,</p> <p>18 obliterating or rendering unrecognizable</p> <p>19 any precursor lesion that may be</p> <p>20 present. Furthermore, identification of</p> <p>21 a putative precursor lesion is based on</p> <p>22 microscopic examination of a complete</p> <p>23 resection; and, therefore, the natural</p> <p>24 history of the lesion cannot be</p> <p>25 observed."</p>	<p style="text-align: right;">Page 156</p> <p>1 end-stage disease; right?</p> <p>2 MS. AHERN: Object to the form.</p> <p>3 THE WITNESS: You're said saying "most," and I</p> <p>4 don't agree with "most."</p> <p>5 BY MR. DEARING:</p> <p>6 Q You don't agree with "most"?</p> <p>7 A No.</p> <p>8 Q Okay. Some?</p> <p>9 A Some, yeah. Some might be obliterated.</p> <p>10 Q Can you put a percentage on how many ovarian</p> <p>11 cancer cases you've looked at under a microscope where</p> <p>12 you've observed precursor lesions?</p> <p>13 MS. AHERN: Objection. Form.</p> <p>14 THE WITNESS: I can't give you a number.</p> <p>15 BY MR. DEARING:</p> <p>16 Q Is it half?</p> <p>17 A I've seen a lot of them. I can't give you --</p> <p>18 over the years. I can't give you a number.</p> <p>19 Q How about in the last ten years?</p> <p>20 MS. AHERN: Objection. Form.</p> <p>21 THE WITNESS: Doesn't make any difference. I would</p> <p>22 see ovarian cancers -- I'd see maybe 30 cases in a week</p> <p>23 or two weeks. It's a large number of cases. Do I</p> <p>24 remember how many I've seen with STICs? It's</p> <p>25 impossible.</p>
<p style="text-align: right;">Page 155</p> <p>1 So do you agree with that statement as it's</p> <p>2 written in your textbook?</p> <p>3 MS. AHERN: Objection. Form.</p> <p>4 THE WITNESS: Can I -- I couldn't really read it.</p> <p>5 Let me just see it. I'm sure you are right.</p> <p>6 So you're talking about the underlined area.</p> <p>7 Okay. "The study of precursor" --</p> <p>8 Well, you read it correctly. That's what is</p> <p>9 stated. This edition was published in 2011. A lot has</p> <p>10 changed since then. It is 2019 now. More and more</p> <p>11 data coming out. And the study that I just mentioned</p> <p>12 to you, which I think is very persuasive, is that in</p> <p>13 some instances the precursor lesion is obliterated;</p> <p>14 however, those cancers -- and that's proven by the fact</p> <p>15 that those cancers in which we don't see a STIC are the</p> <p>16 same on a molecular analysis as ovarian carcinomas in</p> <p>17 which we do see a STIC, suggesting that, in some</p> <p>18 instances, it's overgrown but not in all by any</p> <p>19 instance. You know, we've learned a lot since 2011.</p> <p>20 BY MR. DEARING:</p> <p>21 Q Sure. Well, no matter how advanced the</p> <p>22 science has become in the last eight years, it doesn't</p> <p>23 change the fact that most of the precursor lesions get</p> <p>24 obliterated by the tumor, right, because, by the time</p> <p>25 they're clinical, most of these poor women are in</p>	<p style="text-align: right;">Page 157</p> <p>1 BY MR. DEARING:</p> <p>2 Q I'm not asking for a number, but it seems if</p> <p>3 you observed precursor lesions, that's something that</p> <p>4 would stand out in your mind, wouldn't it?</p> <p>5 MS. AHERN: Objection. Form.</p> <p>6 THE WITNESS: Well, not really.</p> <p>7 BY MR. DEARING:</p> <p>8 Q Are you even looking for precursor lesions</p> <p>9 when you're doing a surgical pathology evaluation?</p> <p>10 A Of course we look for them.</p> <p>11 Q So you look for them in every case?</p> <p>12 A Every case when the tissue is available, yeah.</p> <p>13 Q So you look for them in every case but you</p> <p>14 have no idea how often you find them?</p> <p>15 MS. AHERN: Objection. Form.</p> <p>16 THE WITNESS: I can't give you a number.</p> <p>17 BY MR. DEARING:</p> <p>18 Q So what has specifically developed in the</p> <p>19 science that changed from "rarely seen" to "often seen"</p> <p>20 in the last nine -- last eight years?</p> <p>21 MS. AHERN: Objection. Form. Mischaracterizes</p> <p>22 testimony.</p> <p>23 THE WITNESS: I didn't -- I'll repeat the same</p> <p>24 thing again. In some instances, you can see a STIC</p> <p>25 lesion and a high-grade serous carcinoma. In other</p>

40 (Pages 154 to 157)

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<p style="text-align: right;">Page 158</p> <p>1 instances -- and I can't give you a percentage -- you</p> <p>2 will not see a STIC lesion and a similar-looking</p> <p>3 high-grade serous carcinoma, which we believe is due to</p> <p>4 the fact that that STIC lesion has been overgrown by</p> <p>5 the carcinoma. That's all I can say.</p> <p>6 BY MR. DEARING:</p> <p>7 Q I should have started with that statement.</p> <p>8 So in some cases where you don't see a</p> <p>9 precursor lesion, do you -- do you still attribute</p> <p>10 precursor lesions to be the carcinogenesis of the</p> <p>11 tumor?</p> <p>12 MS. AHERN: Objection. Form.</p> <p>13 THE WITNESS: Well, based on that study that I</p> <p>14 mentioned to you a few minutes ago, that's what we're</p> <p>15 saying, yes.</p> <p>16 BY MR. DEARING:</p> <p>17 Q Okay. Let's talk about something else.</p> <p>18 Do you believe that the introduction of</p> <p>19 foreign material through the vagina and uterine cavity</p> <p>20 can cause inflammation and play an important role in</p> <p>21 ovarian carcinogenesis?</p> <p>22 MS. AHERN: Objection. Form.</p> <p>23 THE WITNESS: Could you specifically tell me what</p> <p>24 you're thinking about? What -- what are you referring</p> <p>25 to?</p>	<p style="text-align: right;">Page 160</p> <p>1 menstruation-induced salpingitis or by</p> <p>2 the introduction of foreign material</p> <p>3 through the vagina and uterine cavity</p> <p>4 plays an important role in ovarian</p> <p>5 carcinogenesis. Evidence of a</p> <p>6 pro-inflammatory microenvironment in</p> <p>7 endometriosis supports this hypothesis</p> <p>8 for type 1 tumors. High-grade serous</p> <p>9 carcinomas are associated with chronic</p> <p>10 salpingitis in 53 percent of cases</p> <p>11 significantly more often than 23 percent</p> <p>12 seen in nonserous tumors, lending</p> <p>13 circumstantial support to this</p> <p>14 hypothesis."</p> <p>15 So this hypothesis about inflammation, and</p> <p>16 particularly the part about introduction of foreign</p> <p>17 material through the vagina and uterine cavity, is that</p> <p>18 a plausible mechanism for inflammation?</p> <p>19 A Let me -- I can see it, but --</p> <p>20 Q The entire section.</p> <p>21 A Yeah, yeah. I just want to check this out.</p> <p>22 I see these references.</p> <p>23 Q By the way, I'm not disagreeing with you --</p> <p>24 with that statement.</p> <p>25 A I notice the first reference is from Ness,</p>
<p style="text-align: right;">Page 159</p> <p>1 BY MR. DEARING:</p> <p>2 Q Your textbook, Chapter 14, just past what we</p> <p>3 read previously.</p> <p>4 MS. AHERN: Page? Sorry.</p> <p>5 MR. DEARING: Let me find it.</p> <p>6 MS. AHERN: Okay.</p> <p>7 MR. DEARING: Oh. I was looking right at it and</p> <p>8 just didn't see it.</p> <p>9 BY MR. DEARING:</p> <p>10 Q Under your section entitled "Inflammation."</p> <p>11 MS. AHERN: Page, I'm sorry.</p> <p>12 MR. DEARING: I'm sorry, page 682.</p> <p>13 MS. AHERN: Thank you.</p> <p>14 MR. DEARING: Chapter 14.</p> <p>15 Let me see if I can blow this up so we can all</p> <p>16 see it.</p> <p>17 BY MR. DEARING:</p> <p>18 Q It says under "Inflammation" -- and, again,</p> <p>19 we're in the chapter called "Serous Epithelial Tumors</p> <p>20 of the Ovary." And specifically, we're talking about</p> <p>21 etiology and risk factors.</p> <p>22 "Inflammation: It has been</p> <p>23 suggested that inflammation potentially</p> <p>24 cited by ovulation-induced surface</p> <p>25 damage by retrograde</p>	<p style="text-align: right;">Page 161</p> <p>1 who's written on this subject. And I don't say I</p> <p>2 entirely agree with her. In fact, I don't.</p> <p>3 287 -- who has been an expert witness for</p> <p>4 plaintiffs.</p> <p>5 287...</p> <p>6 Q Did you believe her before she became an</p> <p>7 expert witness for plaintiffs?</p> <p>8 A No.</p> <p>9 287. Gee, you know, I'm not sure that that</p> <p>10 reference is correct. I'd have to read the article</p> <p>11 specifically because it's -- the title of the article</p> <p>12 is "The Fallopian Tube: Primary Site of Most Pelvic</p> <p>13 High-Grade Serous Carcinomas." It doesn't say anything</p> <p>14 about retrograde menstruation, but anyway. So it would</p> <p>15 be nice to see that reference.</p> <p>16 And then, finally, evidence of -- type 1</p> <p>17 tumors. Let's see, 95. Okay.</p> <p>18 So your question, yes, that's stated. I said</p> <p>19 that there's problems with the -- with the references.</p> <p>20 Q Right. But the studies that pertain to that</p> <p>21 topic that are referenced here, that is the proposition</p> <p>22 of those studies, right, that those three things,</p> <p>23 either the ovulation-induced surface damage or the</p> <p>24 retrograde menstruation or the introduction of foreign</p> <p>25 material through the vagina and uterine cavity, play an</p>

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<p style="text-align: right;">Page 162</p> <p>1 important role in ovarian carcinogenesis?</p> <p>2 A I have to remind you that the inflammation</p> <p>3 that is described there is entirely different from the</p> <p>4 inflammation induced by talc, one being -- the latter</p> <p>5 being a foreign-body giant cell reaction and this being</p> <p>6 the usual type of chronic inflammation.</p> <p>7 Q Well, you use the words "introduction of</p> <p>8 foreign material through the vagina and uterine</p> <p>9 cavity." So it may not be talc, but you're talking</p> <p>10 about a foreign material that would evoke the kind of</p> <p>11 response you're talking -- the kind of foreign-body</p> <p>12 reaction you're talking about; right?</p> <p>13 MS. AHERN: Objection. Form.</p> <p>14 THE WITNESS: I'll have to say that it's in there.</p> <p>15 It's quite speculative.</p> <p>16 BY MR. DEARING:</p> <p>17 Q All right. Did you believe that to be true in</p> <p>18 2011 when you published this book?</p> <p>19 A Well, you know, again, what was in there was</p> <p>20 what we felt at the time.</p> <p>21 Q By the way, the Ness study --</p> <p>22 A Yeah.</p> <p>23 Q -- that it cites --</p> <p>24 A Yeah.</p> <p>25 Q -- is a talc study, isn't it?</p>	<p style="text-align: right;">Page 164</p> <p>1 Q So -- but you chose to cite the articles that</p> <p>2 do support that proposition, that these foreign</p> <p>3 particles can migrate through the female genital tract;</p> <p>4 right?</p> <p>5 A That's what --</p> <p>6 MS. AHERN: Objection.</p> <p>7 THE WITNESS: -- was --</p> <p>8 BY MR. DEARING:</p> <p>9 Q You don't even reference the ones that don't</p> <p>10 suggest that, do you?</p> <p>11 MS. AHERN: Objection. Form. Misstates what the</p> <p>12 actual text says and what his testimony has been.</p> <p>13 BY MR. DEARING:</p> <p>14 Q You didn't offer the -- any alternative</p> <p>15 suggestion in this short chapter on inflammation that</p> <p>16 suggests foreign materials cannot pass through the</p> <p>17 vagina and uterine cavity; right?</p> <p>18 MS. AHERN: Objection. Form. That's a section on</p> <p>19 inflammation, not migration.</p> <p>20 MR. DEARING: I'm sorry. I meant to say</p> <p>21 "inflammation."</p> <p>22 THE WITNESS: Again, the inflammation is not the</p> <p>23 type that we see with talc.</p> <p>24 BY MR. DEARING:</p> <p>25 Q Do you agree, over time, that chronic</p>
<p style="text-align: right;">Page 163</p> <p>1 A I'll have to read the article.</p> <p>2 Q You would at least agree that the introduction</p> <p>3 of foreign material through the vagina and uterine</p> <p>4 cavity was biologically plausible to you when you wrote</p> <p>5 it, right, or you wouldn't put it in your textbook?</p> <p>6 MS. AHERN: Objection. Form.</p> <p>7 THE WITNESS: Again, as I said, a textbook reflects</p> <p>8 the general consensus of what's out there.</p> <p>9 BY MR. DEARING:</p> <p>10 Q Okay.</p> <p>11 A It may not necessarily reflect my own personal</p> <p>12 opinion about it because we have to be fair and</p> <p>13 acknowledge what's out there.</p> <p>14 Q So the general consensus out there is that the</p> <p>15 introduction of foreign material through the vagina --</p> <p>16 A I didn't say the general consensus. I said --</p> <p>17 Q You did. Those were your words.</p> <p>18 A Well, I misspoke.</p> <p>19 I said that there -- those studies are out</p> <p>20 there; people believe it, and that's what was reflected</p> <p>21 in the textbook.</p> <p>22 Q There are also studies out there that --</p> <p>23 presumably, that suggest that particles can't migrate</p> <p>24 through the vagina.</p> <p>25 A That's true.</p>	<p style="text-align: right;">Page 165</p> <p>1 inflammation in gynecologic tissue can cause DNA damage</p> <p>2 and maybe cancer?</p> <p>3 MS. AHERN: Objection. Form.</p> <p>4 THE WITNESS: Could you be more specific and repeat</p> <p>5 that question.</p> <p>6 BY MR. DEARING:</p> <p>7 Q Do you believe that, over time, chronic</p> <p>8 inflammation in a particular part of gynecologic tissue</p> <p>9 can cause DNA damage and result in some type of</p> <p>10 gynecologic cancer?</p> <p>11 MS. AHERN: Objection. Form.</p> <p>12 THE WITNESS: Well, when we -- when we talk about</p> <p>13 causation and initiation of cancer, it has to be viewed</p> <p>14 at the earliest stage, at a nonlesion that, as a result</p> <p>15 of, in this case, inflammation, undergoes neoplastic</p> <p>16 change.</p> <p>17 You can see inflammation in well-formed tumors</p> <p>18 that can be associated with factors that -- cytokines</p> <p>19 or chemokines, whatever -- that participate in the</p> <p>20 progression of a tumor, but that's not initiation.</p> <p>21 That's not causation. And that's what we're really</p> <p>22 talking about.</p> <p>23 BY MR. DEARING:</p> <p>24 Q Do you believe that, with regard to peritoneal</p> <p>25 malignancies, apart from asbestos, radiation, chronic</p>



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<p>1 inflammation, organic chemicals, and nonasbestos 2 mineral fibers may be etiologic agents in some cases? 3 MS. AHERN: Objection. Form. 4 THE WITNESS: Are you reading this from someplace? 5 BY MR. DEARING: 6 Q I'm reading it right off my outline 7 regarding -- 8 A Yeah. But does your outline come from 9 something? 10 Q It comes from several places, but let me ask 11 you the question again if you didn't get it. 12 I'm referring to peritoneal malignancies. 13 Okay. Aside from asbestos, radiation, chronic 14 inflammation, organic chemicals, and nonasbestos 15 mineral fibers may be etiologic agents in some cases. 16 MS. AHERN: Objection. Form. 17 BY MR. DEARING: 18 Q Do you agree with that? 19 A I'd like to see where you're quoting that 20 from. 21 Q Do you agree with that statement or not? 22 A I want to see what you're quoting. I'm not 23 going to just make a comment. 24 Q You don't have an opinion about it? 25 MS. AHERN: Check the prompter because I think that</p>	<p>1 nonasbestos mineral fibers may be an etiologic agent of 2 some peritoneal malignancies? 3 THE WITNESS: What -- 4 MS. AHERN: Objection. Form. 5 THE WITNESS: I'm sorry. 6 MS. AHERN: Go ahead. 7 THE WITNESS: What peritoneal malignancies are you 8 talking about? 9 BY MR. DEARING: 10 Q Any peritoneal malignancies. Think of any 11 kind you want. 12 A The only peritoneal malignancy is malignant 13 mesothelioma. That's the only one there is. 14 Q Well, maybe I'm coming at this the wrong way. 15 How do you define the phrase "etiologic 16 agent"? 17 MS. AHERN: Objection. Form. 18 THE WITNESS: How do you define it? 19 BY MR. DEARING: 20 Q Well, let's find out. 21 I'm looking at Chapter 13 of your book, which 22 is written by Dr. Julie Irving and Dr. Philip Clement. 23 Did you edit this chapter? 24 A Well, I edited the textbook. 25 Q Did you edit this chapter?</p>
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<p>1 your sentence is incomplete, which is what's confusing 2 him and me. 3 Can you go back up. 4 MR. DEARING: I can ask the question again. 5 MS. AHERN: Go back up and take a look at it in 6 writing. It might help. 7 MR. DEARING: Okay. Let me ask this question 8 again. 9 BY MR. DEARING: 10 Q I think I asked it right the first time, so 11 I'm going to say it slowly. 12 With regard to peritoneal malignancies -- 13 okay? Talking about peritoneal malignancies. Aside 14 from asbestos -- well, do you believe asbestos can 15 cause peritoneal malignancies? 16 MS. AHERN: Objection. Form. 17 Type? 18 THE WITNESS: That's controversial. It's not 19 clear. 20 BY MR. DEARING: 21 Q Do you have an opinion either way whether -- 22 A I'm not -- it may or may not. I don't think 23 that the data is sufficiently robust to make a comment 24 like that -- a definitive comment like that. 25 Q Well, do you believe chronic inflammation or</p>	<p>1 A I may -- you know, there was three of us, as I 2 mentioned. I'm not sure if I edited that chapter or 3 one of my other co-editors edited it. 4 Q In this chapter, under the subheading 5 "Malignant Mesothelioma" is described "clinical 6 features." And in the third paragraph of that section, 7 starting with "More than 80 percent," that's referring 8 to a study. Halfway through that paragraph, it says: 9 "Asbestos fibers, however, have 10 been identified with special techniques 11 in some of these women." 12 And they're talking about the malignant 13 mesothelioma patients. 14 "Aside from asbestos, radiation, 15 chronic inflammation, organic chemicals 16 and nonasbestos mineral fibers may be 17 etiologic agents in some cases." 18 So in that sentence, what do they mean by 19 "etiologic agents"? 20 A Good question. I'm not sure what they mean. 21 I mean, do they mean they're just present there or do 22 they cause it? Not clear to me. 23 Q If you were to use the term "etiologic agent," 24 what would it mean to you? 25 A Well, I've never -- I can't remember using it</p>

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<p style="text-align: right;">Page 170</p> <p>1 in that context. I don't use it. It's not something I</p> <p>2 use.</p> <p>3 Q Would you consider asbestos to be an etiologic</p> <p>4 agent of mesothelioma?</p> <p>5 A In some instances, it might be, yes. But in</p> <p>6 some instances it's not been demonstrated. It's been</p> <p>7 much more clearly demonstrated in the pleura than it</p> <p>8 has been in the peritoneum.</p> <p>9 Q Would you agree that the HPV virus is a</p> <p>10 etiologic agent of gynecologic cancers -- of some</p> <p>11 gynecologic cancers?</p> <p>12 MS. AHERN: Objection. Form.</p> <p>13 THE WITNESS: Of cervical cancers and vulvar and</p> <p>14 vaginal cancers, it is the causative agent.</p> <p>15 BY MR. DEARING:</p> <p>16 Q So when a scientist or pathologist like</p> <p>17 yourself uses the term "etiology," you're essentially</p> <p>18 talking about a causative agent, aren't you?</p> <p>19 MS. AHERN: Objection. Form.</p> <p>20 THE WITNESS: Well, as I just said a moment ago,</p> <p>21 some may refer to it in that way. I don't necessarily.</p> <p>22 BY MR. DEARING:</p> <p>23 Q Would you -- how would you use the term</p> <p>24 "etiology"? What does it mean to you?</p> <p>25 A Why don't we just look it up, and we can all</p>	<p style="text-align: right;">Page 172</p> <p>1 etiology means to you.</p> <p>2 Do you agree with that definition?</p> <p>3 A That definition just said that. It says</p> <p>4 "causing or contributing."</p> <p>5 Q Okay. So let's substitute that word in this</p> <p>6 phrase.</p> <p>7 Aside from asbestos, with regard to malignant</p> <p>8 mesotheliomas, do you think that nonasbestos mineral</p> <p>9 fibers may cause or contribute to cause malignant</p> <p>10 mesotheliomas in some cases?</p> <p>11 MS. AHERN: Objection. Form.</p> <p>12 THE WITNESS: Interesting they don't reference that</p> <p>13 point.</p> <p>14 BY MR. DEARING:</p> <p>15 Q I'm reading it.</p> <p>16 A Yeah, I know. I'm saying it's interesting</p> <p>17 that that point wasn't referenced with a citation.</p> <p>18 Q Oh, I got you. Okay.</p> <p>19 Well, it's clearly the opinion of the two</p> <p>20 authors of this chapter; right?</p> <p>21 A The two authors, yes.</p> <p>22 Q And this is a chapter you edited; right?</p> <p>23 MS. AHERN: Objection. Form.</p> <p>24 THE WITNESS: Like I said, I'm not sure that I</p> <p>25 edited it.</p>
<p style="text-align: right;">Page 171</p> <p>1 decide -- agree on it?</p> <p>2 Q Okay. I don't want to impose a definition on</p> <p>3 you.</p> <p>4 A Okay.</p> <p>5 Q But according to Google --</p> <p>6 A Google, huh? That's definitive.</p> <p>7 MR. ROTMAN: According to the dictionary --</p> <p>8 BY MR. DEARING:</p> <p>9 Q Well, let me ask you if you agree with this</p> <p>10 definition.</p> <p>11 Is the medical definition of etiological --</p> <p>12 and it says, "causing or contributing to the</p> <p>13 development of a disease or condition." That's what it</p> <p>14 meant to me.</p> <p>15 Is that what it means to you?</p> <p>16 A Causing or what?</p> <p>17 MS. AHERN: Contributing.</p> <p>18 THE WITNESS: Contributing.</p> <p>19 BY MR. DEARING:</p> <p>20 Q Causing or contributing to cause a medical</p> <p>21 condition.</p> <p>22 A Causing or contributing?</p> <p>23 Q Yes.</p> <p>24 A Well, again, contributing isn't cause.</p> <p>25 Q I didn't ask you that. I'm asking you what</p>	<p style="text-align: right;">Page 173</p> <p>1 BY MR. DEARING:</p> <p>2 Q Okay. I'm sorry. I missed that.</p> <p>3 So when you talk about cause or contributing</p> <p>4 to cause, what's the distinction between those two</p> <p>5 ideas, in your mind?</p> <p>6 MS. AHERN: Objection. Form.</p> <p>7 THE WITNESS: "Causation," to me, means that it's</p> <p>8 an initiating factor in setting the process off.</p> <p>9 "Contributing," to me, means that possibly the process</p> <p>10 is in place and it contributes to its further</p> <p>11 progression.</p> <p>12 BY MR. DEARING:</p> <p>13 Q So contributing to cause, in your mind, is</p> <p>14 something that assists the progression of something</p> <p>15 that already exists?</p> <p>16 MS. AHERN: Objection.</p> <p>17 BY MR. DEARING:</p> <p>18 Q Is that what you're saying?</p> <p>19 A I didn't say "contributing." I separated</p> <p>20 "cause" and "contribution."</p> <p>21 Q Okay. I want to talk about "cause" and</p> <p>22 "contributing to cause."</p> <p>23 Is there any distinction between those two</p> <p>24 terms?</p> <p>25 MS. AHERN: Objection. Form. Asked and answered.</p>

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<p style="text-align: right;">Page 174</p> <p>1 THE WITNESS: Can I see that book again, please. I</p> <p>2 still can't read that.</p> <p>3 BY MR. DEARING:</p> <p>4 Q I'm not talking about that section now, but...</p> <p>5 A Oh, you're not?</p> <p>6 Q No. I'm just generally wanting to get your</p> <p>7 opinion on --</p> <p>8 A Oh, I see.</p> <p>9 Q -- "causing" or "contributing to cause."</p> <p>10 A Oh, I thought you were referring to that</p> <p>11 sentence. Oh, so we're not?</p> <p>12 Q No. That sentence uses the word "etiologic</p> <p>13 agent."</p> <p>14 A Uh-huh.</p> <p>15 MS. AHERN: Whatever you meant by that.</p> <p>16 BY MR. DEARING:</p> <p>17 Q So in your mind, is there any distinction</p> <p>18 between contributing to cause something and causing</p> <p>19 something?</p> <p>20 MS. AHERN: Objection. Form. Asked and answered</p> <p>21 very clearly just two minutes ago.</p> <p>22 THE WITNESS: Causation is one issue. Contributing</p> <p>23 is another. They're not the same.</p> <p>24 BY MR. DEARING:</p> <p>25 Q I don't mean contributing. I mean</p>	<p style="text-align: right;">Page 176</p> <p>1 MS. AHERN: Objection. Form.</p> <p>2 THE WITNESS: Well, I think you've got it twisted</p> <p>3 around anyway.</p> <p>4 BY MR. DEARING:</p> <p>5 Q Okay. Well, correct me.</p> <p>6 A It starts with initiation, and proliferation</p> <p>7 may be the next step. And then another step may, after</p> <p>8 that, be promotion and then progression.</p> <p>9 Q So when you use the term "cause" or</p> <p>10 "contribute to cause," are you referring to the</p> <p>11 initiation phase of that process or the promotion phase</p> <p>12 or both?</p> <p>13 MS. AHERN: Objection. Form. He's never said that</p> <p>14 he uses those terms.</p> <p>15 THE WITNESS: I don't use "contributing to cause"</p> <p>16 how you understand it. I'm just saying "causation."</p> <p>17 That, to me, is initiation, period.</p> <p>18 BY MR. DEARING:</p> <p>19 Q If gynecologic cancers are multifactorial and</p> <p>20 they may have more than one cause, do you agree that</p> <p>21 there may be more than one thing contributing to cause</p> <p>22 them?</p> <p>23 MS. AHERN: Objection. Form.</p> <p>24 THE WITNESS: There may be multiple causes for a</p> <p>25 neoplasm to begin, to get an issue, maybe multiple</p>
<p style="text-align: right;">Page 175</p> <p>1 contributing to cause. Okay? You're only giving me</p> <p>2 half of the phrase.</p> <p>3 MS. AHERN: Objection.</p> <p>4 BY MR. DEARING:</p> <p>5 Q Is there a distinction between contributing to</p> <p>6 a disease and -- I'm sorry.</p> <p>7 Is there a distinction between contributing to</p> <p>8 cause a disease and causing a disease? Is there any</p> <p>9 distinction there?</p> <p>10 A To me, yes.</p> <p>11 MS. AHERN: Objection. Form.</p> <p>12 THE WITNESS: To me, causation is much stronger.</p> <p>13 Contributing may be involved; may not be. It's much</p> <p>14 more wishy-washy.</p> <p>15 BY MR. DEARING:</p> <p>16 Q Do you agree that almost all gynecologic</p> <p>17 cancers are multifactorial in that they may have more</p> <p>18 than one cause?</p> <p>19 A Yes, that's probably true.</p> <p>20 Q Do you believe in the cancer progression model</p> <p>21 of initiation, promotion, proliferation?</p> <p>22 MS. AHERN: Objection. Form.</p> <p>23 BY MR. DEARING:</p> <p>24 Q Do you agree that that's a reasonable cancer</p> <p>25 model?</p>	<p style="text-align: right;">Page 177</p> <p>1 causes.</p> <p>2 BY MR. DEARING:</p> <p>3 Q So for the last time, breaking down that</p> <p>4 sentence again, coming back full circle now, do you</p> <p>5 agree that asbestos can be an etiologic agent of some</p> <p>6 cancers --</p> <p>7 MS. AHERN: Objection. Form.</p> <p>8 BY MR. DEARING:</p> <p>9 Q -- of some mesotheliomas?</p> <p>10 MS. AHERN: Objection. Form.</p> <p>11 THE WITNESS: Yes, it may be.</p> <p>12 BY MR. DEARING:</p> <p>13 Q And do you believe chronic inflammation can be</p> <p>14 a cause of malignant mesotheliomas?</p> <p>15 MS. AHERN: Objection. Form.</p> <p>16 THE WITNESS: Again, I'd like to see the data for</p> <p>17 that.</p> <p>18 BY MR. DEARING:</p> <p>19 Q So you have no opinion on that without looking</p> <p>20 at a --</p> <p>21 A Yeah, I don't -- I don't agree with that.</p> <p>22 Q Okay. And do you believe that nonasbestos</p> <p>23 mineral fibers can be a etiologic agent or cause of</p> <p>24 some malignant mesotheliomas?</p> <p>25 MS. AHERN: Objection. Form.</p>

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<p style="text-align: right;">Page 178</p> <p>1 THE WITNESS: Same thing, I don't -- I'd like to</p> <p>2 see the data that they're alluding to.</p> <p>3 BY MR. DEARING:</p> <p>4 Q Well, you would at least agree with me that</p> <p>5 the two authors of that chapter believe that, wouldn't</p> <p>6 you?</p> <p>7 MS. AHERN: Objection. Form.</p> <p>8 THE WITNESS: The two authors appear to believe</p> <p>9 that.</p> <p>10 MR. DEARING: Mind if we take a break?</p> <p>11 MS. AHERN: Sure.</p> <p>12 VIDEO OPERATOR BROWN: Time is now 2:15. Going off</p> <p>13 the record.</p> <p>14 (Recess taken.)</p> <p>15 VIDEO OPERATOR BROWN: The time is now 2:34. Back</p> <p>16 on the record.</p> <p>17 BY MR. DEARING:</p> <p>18 Q Doctor, you said earlier that you expect that</p> <p>19 talc exposure would elicit a foreign-body giant cell</p> <p>20 granulomatous response within the body; right?</p> <p>21 A That's correct.</p> <p>22 Q Would asbestos fibers invoke that same type of</p> <p>23 response?</p> <p>24 A I really am not an expert on asbestos --</p> <p>25 asbestosis, but I'm not aware of it doing foreign</p>	<p style="text-align: right;">Page 180</p> <p>1 don't know.</p> <p>2 Q Would you expect the stromal tissue to react</p> <p>3 the same way the epithelial tissue would react in</p> <p>4 humans?</p> <p>5 A Well, they're different. So I don't know how</p> <p>6 it would react.</p> <p>7 Q If talc can cause p53 mutations in tubal</p> <p>8 cells, would you expect that it could also cause</p> <p>9 cancer?</p> <p>10 MS. AHERN: Objection. Form.</p> <p>11 THE WITNESS: Are you speculating that, or has</p> <p>12 it -- I haven't seen data to that effect.</p> <p>13 BY MR. DEARING:</p> <p>14 Q Right. I'm asking -- I'm asking</p> <p>15 hypothetically right now. If talc could evoke a p53</p> <p>16 mutation in tubal cells, do you think that talc could</p> <p>17 cause cancer in tubal cells?</p> <p>18 A Not necessarily.</p> <p>19 Q Same with ovarian cells?</p> <p>20 MS. AHERN: Objection. Form.</p> <p>21 BY MR. DEARING:</p> <p>22 Q If talc could evoke a p53 mutation in ovarian</p> <p>23 cells, do you think it could cause cancer?</p> <p>24 MS. AHERN: Objection. Form.</p> <p>25 THE WITNESS: Not necessarily.</p>
<p style="text-align: right;">Page 179</p> <p>1 body -- I really -- best thing not to get into that</p> <p>2 because it's not something I deal with.</p> <p>3 Q Have you ever looked at pulmonary tissue of</p> <p>4 someone suffering from mesothelioma?</p> <p>5 A No, I haven't.</p> <p>6 Q So you've never observed asbestos in tissue at</p> <p>7 all?</p> <p>8 A That's right.</p> <p>9 Q Well, can you think of any reason why asbestos</p> <p>10 wouldn't evoke the same kind of foreign-body reaction</p> <p>11 that talc would?</p> <p>12 MS. AHERN: Objection. Form.</p> <p>13 THE WITNESS: Different agents do different things.</p> <p>14 BY MR. DEARING:</p> <p>15 Q Do you think that stroma contributes to the</p> <p>16 development of ovarian cancer or tubal cancers?</p> <p>17 MS. AHERN: Objection. Form.</p> <p>18 BY MR. DEARING:</p> <p>19 Q Or STIC?</p> <p>20 A It might.</p> <p>21 Q How might the stroma contribute to the</p> <p>22 development of tubal cancer or ovarian cancer?</p> <p>23 A Well, in many cancers, there's an interaction</p> <p>24 between the epithelium and the stroma. So it's</p> <p>25 certainly possible. I wouldn't rule it out, but I</p>	<p style="text-align: right;">Page 181</p> <p>1 BY MR. DEARING:</p> <p>2 Q You answered both of those questions with "not</p> <p>3 necessarily."</p> <p>4 A Correct.</p> <p>5 Q Does that mean you don't know, or does that</p> <p>6 mean you don't think so, or it could?</p> <p>7 MS. AHERN: Objection. Form.</p> <p>8 THE WITNESS: Well --</p> <p>9 BY MR. DEARING:</p> <p>10 Q Let me ask the question again.</p> <p>11 A P53 signatures have p53 mutations. They don't</p> <p>12 all go to STIC. STIC has p53 mutations. They don't</p> <p>13 all go on to invasive cancers. Just having a p53</p> <p>14 mutation doesn't mean it's inevitably going to become</p> <p>15 cancer.</p> <p>16 Q Right. I'm not saying it necessary would</p> <p>17 become cancer, but if talc can evoke a p53 response in</p> <p>18 tubal cells or ovarian cells, would that be evidence to</p> <p>19 you that talc could cause cancer?</p> <p>20 MS. AHERN: Objection. Form.</p> <p>21 THE WITNESS: No.</p> <p>22 BY MR. DEARING:</p> <p>23 Q Do you agree that one example of inflammation</p> <p>24 associated with foreign materials includes macrophages?</p> <p>25 MS. AHERN: Objection. Form.</p>

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<p style="text-align: right;">Page 182</p> <p>1 THE WITNESS: Well, macrophages in tissue become</p> <p>2 histiocytes, and that's part of a foreign-body giant</p> <p>3 cell granuloma.</p> <p>4 BY MR. DEARING:</p> <p>5 Q A minute ago, when I asked you about talc</p> <p>6 eliciting a p53 response and I asked you whether you</p> <p>7 thought that would be evidence that talc could cause</p> <p>8 cancer in those cells, why did you say no?</p> <p>9 MS. AHERN: Objection. Form.</p> <p>10 THE WITNESS: Because, as I said, having a p53</p> <p>11 mutation, in and of itself, does not inevitably mean a</p> <p>12 tissue is going to become malignant.</p> <p>13 BY MR. DEARING:</p> <p>14 Q Is it suggestive that a tissue might become</p> <p>15 malignant?</p> <p>16 MS. AHERN: Objection. Form.</p> <p>17 THE WITNESS: Not necessarily.</p> <p>18 BY MR. DEARING:</p> <p>19 Q What does that mean, "not necessarily"?</p> <p>20 A As I said, you can have a p53 mutation and</p> <p>21 have a perfectly benign lesion.</p> <p>22 Q You said a while ago that one reason you don't</p> <p>23 believe talc causes ovarian cancer is because you</p> <p>24 haven't seen talc elicit a foreign-body granulomatous</p> <p>25 reaction in gynecologic tissue. Right? Isn't that</p>	<p style="text-align: right;">Page 184</p> <p>1 BY MR. DEARING:</p> <p>2 Q In your textbook in Chapter 12, written by</p> <p>3 Dr. Irving and Dr. Clement, entitled "Nonneoplastic</p> <p>4 Lesions of the Ovary," the subtitle "foreign-body</p> <p>5 Granulomas," the statement is:</p> <p>6 "A variety of foreign materials may</p> <p>7 evoke a granulomatous reaction on the</p> <p>8 ovarian and extraovarian peritoneal</p> <p>9 surfaces, potentially mimicking</p> <p>10 malignant tumor at operation."</p> <p>11 So the authors here are a bit equivocal about</p> <p>12 whether foreign materials will evoke a granulomatous</p> <p>13 reaction; right? They're saying -- they use the word</p> <p>14 "may" because it doesn't always happen; right?</p> <p>15 MS. AHERN: Objection. Form.</p> <p>16 THE WITNESS: "Variety of foreign materials may</p> <p>17 evoke granulomatous reaction on" -- "may."</p> <p>18 BY MR. DEARING:</p> <p>19 Q Right.</p> <p>20 A That's suggestive, but not definitive at all.</p> <p>21 Q So is it fair to say that sometimes they do</p> <p>22 and sometimes they don't evoke a granulomatous</p> <p>23 reaction?</p> <p>24 MS. AHERN: Objection. Form.</p> <p>25 THE WITNESS: I don't even think they say that.</p>
<p style="text-align: right;">Page 183</p> <p>1 correct?</p> <p>2 A No, that's not the reason I don't think it</p> <p>3 causes cancer.</p> <p>4 Q Tell me why you think talc doesn't cause --</p> <p>5 can't cause cancer.</p> <p>6 A Because there's been absolutely no evidence in</p> <p>7 the literature that it does.</p> <p>8 Q Would you agree with me that foreign materials</p> <p>9 don't always evoke granulomatous reactions in ovarian</p> <p>10 tissue?</p> <p>11 MS. AHERN: Objection. Form.</p> <p>12 BY MR. DEARING:</p> <p>13 Q Or extraperitoneal tissue?</p> <p>14 MS. AHERN: Objection. Form.</p> <p>15 THE WITNESS: I haven't evaluated other foreign</p> <p>16 bodies or agents.</p> <p>17 BY MR. DEARING:</p> <p>18 Q So are you agreeing or disagreeing or do you</p> <p>19 not know that foreign materials don't always evoke</p> <p>20 granulomatous reaction on ovarian and extraovarian</p> <p>21 peritoneal services?</p> <p>22 MS. AHERN: Objection. Form. Asked and answered.</p> <p>23 THE WITNESS: I'd like to see the data, and then I</p> <p>24 could make a decision. I haven't seen it.</p> <p>25 ///</p>	<p style="text-align: right;">Page 185</p> <p>1 They just say it might.</p> <p>2 BY MR. DEARING:</p> <p>3 Q Is it equally true that it might not?</p> <p>4 MS. AHERN: Objection. Form.</p> <p>5 THE WITNESS: Well, may not.</p> <p>6 BY MR. DEARING:</p> <p>7 Q Do you agree that whether the body reacts to a</p> <p>8 foreign particle by macrophage or granuloma depends in</p> <p>9 part on the body's interpretation of that particle and</p> <p>10 its size?</p> <p>11 MS. AHERN: Objection. Form.</p> <p>12 THE WITNESS: I don't know anything about the size</p> <p>13 business. Size.</p> <p>14 BY MR. DEARING:</p> <p>15 Q So you are saying that the size of a foreign</p> <p>16 material is not -- in no way influences whether the</p> <p>17 body tries to sequester that particle with macrophages</p> <p>18 versus giant cell granulomas?</p> <p>19 MS. AHERN: Object to the form.</p> <p>20 THE WITNESS: It may. I mean, different sizes of</p> <p>21 talc may have -- may induce the same thing. I'm not</p> <p>22 sure the size is that relevant.</p> <p>23 BY MR. DEARING:</p> <p>24 Q If a macrophage could engulf a talc particle,</p> <p>25 you wouldn't expect to see a giant cell granulomatous</p>

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<p style="text-align: right;">Page 186</p> <p>1 response, would you?</p> <p>2 MS. AHERN: Objection. Form.</p> <p>3 BY MR. DEARING:</p> <p>4 Q Because the macrophage handles it?</p> <p>5 MS. AHERN: Same objections.</p> <p>6 THE WITNESS: Well, generally speaking, from what</p> <p>7 I've read about it, these particles are too large for a</p> <p>8 single macrophage to envelope it, which results in</p> <p>9 another macrophage coming along with it and membranes</p> <p>10 fuse and they engulf the particle.</p> <p>11 BY MR. DEARING:</p> <p>12 Q Are you referring to talc particles?</p> <p>13 A Yes.</p> <p>14 Q What's your basis for concluding that</p> <p>15 macrophages cannot engulf a talc particle?</p> <p>16 MS. AHERN: Objection. Form.</p> <p>17 THE WITNESS: It's been -- I believe it's been</p> <p>18 stated -- shown in the literature that the particle</p> <p>19 might be too large. It's going -- it's going to elicit</p> <p>20 histiocytic reaction for sure.</p> <p>21 BY MR. DEARING:</p> <p>22 Q Well, do you agree with me that macrophages</p> <p>23 may respond to very small particles whereas granulomas</p> <p>24 may respond to larger particles or larger clusters of</p> <p>25 particles?</p>	<p style="text-align: right;">Page 188</p> <p>1 BY MR. DEARING:</p> <p>2 Q Why do you think he knows nothing about</p> <p>3 gynecologic pathology if you haven't read his stuff?</p> <p>4 A Because he's a pulmonary pathologist.</p> <p>5 Pulmonary pathologists don't look at gynecologic</p> <p>6 specimens.</p> <p>7 Q Well, he's also a general pathologist, a</p> <p>8 surgical pathologist, and he has been a -- well --</p> <p>9 A Well, I'm not impugning his -- I'm just saying</p> <p>10 he's not a gynecologic pathologist. Let's put it that</p> <p>11 way.</p> <p>12 Q Okay. Are you aware that the publications</p> <p>13 he's authored state that the talc particles he</p> <p>14 typically finds in ovarian tissue, in pelvic lymph</p> <p>15 nodes is in the 5-micron range, maybe 1 to 10 microns,</p> <p>16 but average around 5 microns?</p> <p>17 MS. AHERN: Objection. Form. Are you talking</p> <p>18 about publications or litigation reports?</p> <p>19 MR. DEARING: Publications.</p> <p>20 THE WITNESS: I don't remember reading about the</p> <p>21 size of the particles.</p> <p>22 BY MR. DEARING:</p> <p>23 Q If a talc particle found its way into ovarian</p> <p>24 tissue and it was about 5 to 10 microns in size, you</p> <p>25 would expect that to be handled by a macrophage,</p>
<p style="text-align: right;">Page 187</p> <p>1 MS. AHERN: Objection.</p> <p>2 THE WITNESS: I haven't seen data that divides it</p> <p>3 up that way.</p> <p>4 BY MR. DEARING:</p> <p>5 Q You remember who Dr. John Godleski is, don't</p> <p>6 you?</p> <p>7 A I know the name. I know he's involved in this</p> <p>8 litigation.</p> <p>9 Q Right. He testified in the same trial you</p> <p>10 did.</p> <p>11 A Hmm.</p> <p>12 Q And he is a pathologist and a microscopist at</p> <p>13 Harvard. Well, he's retired, but he spent his career</p> <p>14 at Harvard.</p> <p>15 Have you read any of his publications?</p> <p>16 A No.</p> <p>17 Q Have you read any of his opinions about talc</p> <p>18 in tissue, particularly in the size of particles he</p> <p>19 typically finds in tissue?</p> <p>20 MS. AHERN: Objection. Form.</p> <p>21 THE WITNESS: He's a pulmonary pathologist, as I</p> <p>22 recall, knows nothing about gynecologic pathology.</p> <p>23 Having said that, I don't recall specifically reading</p> <p>24 his summation of his opinions regarding the size of</p> <p>25 talc particles.</p>	<p style="text-align: right;">Page 189</p> <p>1 wouldn't you, not a giant cell?</p> <p>2 MS. AHERN: Objection. Form.</p> <p>3 THE WITNESS: You're stating a big "if," namely</p> <p>4 that it gets into ovarian tissue, which I think is --</p> <p>5 BY MR. DEARING:</p> <p>6 Q I'm going to show you pictures of it in</p> <p>7 ovarian tissue in just a minute.</p> <p>8 A I don't care if you show pictures of it. I</p> <p>9 don't think it means it's even there. Biologically, it</p> <p>10 can be a complete contaminant.</p> <p>11 Q So are you saying there's no possible way talc</p> <p>12 can get into any ovarian tissue?</p> <p>13 A Well, it's been described. Let's put it that</p> <p>14 way. It has been described.</p> <p>15 Q What does that mean, "it's been described"?</p> <p>16 I've been describing it all day.</p> <p>17 A It's been described that talc is present in</p> <p>18 ovarian tissue in users or nonusers, as I remember from</p> <p>19 the Heller article.</p> <p>20 Q We can talk about Heller if you like, but the</p> <p>21 fact of the matter is if a talc particle gets to</p> <p>22 ovarian tissue and it's between 1 and 10 microns in</p> <p>23 size, wouldn't you expect that would attract a</p> <p>24 macrophage, not a giant cell?</p> <p>25 MS. AHERN: Objection. Form.</p>

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<p style="text-align: right;">Page 190</p> <p>1 THE WITNESS: I don't -- as I said, I haven't read</p> <p>2 anything about -- specifically about the size of</p> <p>3 particles and whether it's engulfed by a single</p> <p>4 macrophage or by a giant cell.</p> <p>5 BY MR. DEARING:</p> <p>6 Q So if you don't know whether a macrophage</p> <p>7 would respond to it or a giant cell respond to it, how</p> <p>8 can you say that talc can't cause cancer because it</p> <p>9 would evoke a giant cell granulomatous response?</p> <p>10 MS. AHERN: Objection. That's not at all what he</p> <p>11 said.</p> <p>12 THE WITNESS: We have to get back to precursor</p> <p>13 lesions and finding evidence of carcinomatous stimulus</p> <p>14 in those cells, and those are fallopian tube</p> <p>15 epithelium, not ovarian cells.</p> <p>16 (The document referenced below was</p> <p>17 marked Deposition Exhibit 6 for</p> <p>18 identification and is appended hereto.)</p> <p>19 BY MR. DEARING:</p> <p>20 Q I'm handing you a study by Dr. Sandra McDonald</p> <p>21 and others, including Dr. Godleski, entitled</p> <p>22 "Correlative Polarizing Light and Scanning Electron</p> <p>23 Microscopy for the Assessment of Talc in Pelvic Region</p> <p>24 Lymph Nodes."</p> <p>25 Have you ever seen that study? It's fairly</p>	<p style="text-align: right;">Page 192</p> <p>1 Do you have any reason to disagree with that?</p> <p>2 MS. AHERN: Object to the form.</p> <p>3 THE WITNESS: I want to go back and sort of read</p> <p>4 this Materials and Methods a little better.</p> <p>5 BY MR. DEARING:</p> <p>6 Q If you want to take time and read the whole</p> <p>7 study --</p> <p>8 A No, I'm just reading --</p> <p>9 Q -- we can go off the record and you can do</p> <p>10 that.</p> <p>11 A I'm reading materials and methods. I'm up to</p> <p>12 your paragraph.</p> <p>13 Q Keep in mind the question is are these -- one,</p> <p>14 two, three, four, five, six, seven, eight -- eight</p> <p>15 scientists reporting finding talc particles in the 1-</p> <p>16 to 10-micron range in pelvic lymph nodes and</p> <p>17 gynecologic tissue?</p> <p>18 A Okay. So they're finding talc particles in</p> <p>19 lymph nodes, and do they say ovarian tissues here?</p> <p>20 Probably. It is mainly lymph nodes, it sounds like.</p> <p>21 They're focused on the lymph nodes.</p> <p>22 Q They are. You're right.</p> <p>23 A So they find it in lymph nodes, yes. What's</p> <p>24 your question?</p> <p>25 Q The size of the particles they're finding in</p>
<p style="text-align: right;">Page 191</p> <p>1 new. I don't believe it's referenced in your</p> <p>2 materials.</p> <p>3 A Yeah, I don't think I've seen this.</p> <p>4 MS. AHERN: Take your time if you want to read it.</p> <p>5 THE WITNESS: What's your question?</p> <p>6 BY MR. DEARING:</p> <p>7 Q My question is, over on page 3 at the top,</p> <p>8 Dr. McDonald describes the talc being visualized using</p> <p>9 polarizing microscopy, and she says:</p> <p>10 "Talc is readily visible under</p> <p>11 polarizing light microscopy where it may</p> <p>12 be found as both plates and fibrous form</p> <p>13 and where the particles or fibers are</p> <p>14 brightly birefringent and often in the</p> <p>15 size range of 1 to 10 microns."</p> <p>16 MS. AHERN: I'm sorry. Do you have a copy of that?</p> <p>17 MR. DEARING: I do.</p> <p>18 MS. AHERN: Thank you. Page 3.</p> <p>19 MR. DEARING: Page 3.</p> <p>20 BY MR. DEARING:</p> <p>21 Q What she's describing here are talc particles</p> <p>22 that she's seen in ovarian tissue and pelvic lymph</p> <p>23 nodes. And she's saying that the size range that she</p> <p>24 sees and that Dr. Godleski has seen repeatedly is in</p> <p>25 the 1- to 10-micron range.</p>	<p style="text-align: right;">Page 193</p> <p>1 pelvic lymph nodes are 1 to 10 microns, right, as they</p> <p>2 report it?</p> <p>3 A Yes.</p> <p>4 Q And if you would turn over to page 9,</p> <p>5 Figure 3, there's a photomicrograph.</p> <p>6 A Hold on one sec.</p> <p>7 MS. AHERN: Take your time. If you need to go off</p> <p>8 the record, we can.</p> <p>9 THE WITNESS: Okay. What were you saying now? I'm</p> <p>10 sorry.</p> <p>11 BY MR. DEARING:</p> <p>12 Q Okay. Page 9. There are three</p> <p>13 photomicrographs. And I just want to talk about one of</p> <p>14 them.</p> <p>15 Do you see the paragraph that starts</p> <p>16 "Figure 3"?</p> <p>17 A I'm on Figure 4.</p> <p>18 Q Page 9.</p> <p>19 A I see page --</p> <p>20 Q Page 9.</p> <p>21 A Page 9. Yes. Okay.</p> <p>22 Q And the paragraph that starts with the word</p> <p>23 "Figure 3."</p> <p>24 A Yes.</p> <p>25 Q Okay. Figure 3 -- and that's the table above,</p>

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<p style="text-align: right;">Page 194</p> <p>1 but Figure 3 shows "correlative polarizing light 2 microscopy, SEM, and EDX from Case 18 in the digestate 3 study." 4 Below is some photomicrographs. 5 "Going clockwise from upper left, 6 Panel A shows polarized light microscopy 7 showing numerous birefringent particles, 8 general size range 1 to 5 microns within 9 the macrophages of the left external 10 iliac lymph node." 11 Do you see that. 12 A In Figure A? 13 Q Do you see where I'm reading from? 14 A "Going clockwise from upper left Panel A shows 15 polarized light microscopy, H&amp;E" -- 16 A is H&amp;E? It sure doesn't look like an H&amp;E. 17 "-- shows" -- 18 THE REPORTER: Doctor, if you're reading, I'm not 19 picking it up. 20 THE WITNESS: I'm sorry. 21 Figure 3 shows correlative polarizing light 22 microscopy, SEM, and EDX from Case 18 in the digestate 23 study (Table 1). Going clockwise from upper left, 24 Panel A shows polarized light microscopy, H&amp;E, showing 25 numerous birefringent particles, general size from 1 to</p>	<p style="text-align: right;">Page 196</p> <p>1 lymph node." 2 So, again, there's another photomicrograph of 3 birefringent particles being sequestered by 4 macrophages; right? 5 MS. AHERN: Objection. Form. 6 BY MR. DEARING: 7 Q At least according to those six, seven 8 authors? 9 A So what -- I need -- could you read that -- I 10 couldn't follow. I was looking at the pictures. What 11 were you reading exactly? 12 Q The caption underneath the photomicrograph. 13 A Oh. The caption -- 14 MS. AHERN: Just read it to yourself so she doesn't 15 have to write it down. 16 BY MR. DEARING: 17 Q You can stop after A because that's all I'm 18 talking about. 19 A Okay. 20 Q So do you agree with me that that's another 21 photomicrograph showing birefringent particles being 22 engulfed by macrophages? 23 A Well, honestly, I can't tell from this 24 black-and-white photo what they are. I see polarized 25 light and I -- I see polarized, you know, particles,</p>
<p style="text-align: right;">Page 195</p> <p>1 5 micrograms -- microns within the macrophages of the 2 left external iliac lymph node. 3 BY MR. DEARING: 4 Q Right. That's what I want to point out to 5 you. 6 A Yeah. 7 Q Okay. Do you agree that what the authors are 8 saying there is that the birefringent particles 9 observed in the 1- to 5-micron range are being 10 sequestered by macrophages? Right? 11 A Okay. 12 MS. AHERN: Objection. Form. 13 BY MR. DEARING: 14 Q Do you agree with that? 15 A Yeah. 16 Q If you turn the page, there's another 17 photomicrograph on page 11. And, again, they note in 18 the caption underneath it "Numerous birefringent 19 particles under polarized light microscopy" -- 20 MS. AHERN: Where are you? I'm sorry. 21 MR. DEARING: Page 11. 22 BY MR. DEARING: 23 Q "Numerous birefringent particles 24 under polarized light microscopy within 25 the macrophages of a left external iliac</p>	<p style="text-align: right;">Page 197</p> <p>1 but I don't see what they are. 2 Q Do you agree that the eight authors are 3 reporting those to be -- 4 A Well, maybe they are. But they reported that. 5 I don't see it. I can't convince myself on this 6 picture that -- 7 Q I'm not asking you to. I'm asking you to 8 agree with me or not that the eight authors of this 9 paper identify these birefringent particles in this 10 photomicrograph as being engulfed by macrophages. 11 MS. AHERN: Objection. Form. 12 THE WITNESS: Maybe that's what they say, but they 13 don't -- haven't convinced me in the picture. If I 14 were a reviewer, I wouldn't accept that at all. 15 BY MR. DEARING: 16 Q Well, of course not. You would want to see 17 the photomicrograph that they looked at. 18 A Yeah. I mean, they're showing this picture, 19 but it's a gemish, black and white, some little white 20 particles. I can't tell if it's a macrophage or not. 21 Q If you will turn next to the discussion 22 section. That's the next page. 23 A Okay. 24 Q The scientists write: 25 "The accurate identification of</p>

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<p style="text-align: right;">Page 198</p> <p>1 talc in pelvic tissues is important</p> <p>2 because it documents exposure by</p> <p>3 demonstrating the presence of talc in</p> <p>4 these tissues and provides evidence and</p> <p>5 support of the role of talc in the</p> <p>6 epidemiological association with ovarian</p> <p>7 cancer in case-control studies."</p> <p>8 A Yes.</p> <p>9 Q Do you agree that the evidence of talc found</p> <p>10 within the tissue being engulfed by macrophages is</p> <p>11 evidence of talc exposure?</p> <p>12 MS. AHERN: Objection. Form. He just said he</p> <p>13 couldn't tell they were being engulfed by macrophages.</p> <p>14 BY MR. DEARING:</p> <p>15 Q Well, if you presume those talc particles are</p> <p>16 being engulfed by macrophages and that these six</p> <p>17 authors are correct in what they observed --</p> <p>18 A That doesn't --</p> <p>19 Q -- do you believe that that's evidence of</p> <p>20 exposure?</p> <p>21 A It doesn't convince me. I'm not convinced by</p> <p>22 these photos, frankly.</p> <p>23 Q I'm not asking you to be convinced by the</p> <p>24 photos.</p> <p>25 A Well, there were six authors. Doesn't matter.</p>	<p style="text-align: right;">Page 200</p> <p>1 BY MR. DEARING:</p> <p>2 Q Okay. Well, presume for me, if you would,</p> <p>3 that they're right, that they are looking at talc</p> <p>4 particles in the 1- to 5-micron range being engulfed by</p> <p>5 macrophages.</p> <p>6 Do you agree with me, if they're correct, that</p> <p>7 that's evidence of exposure to talc?</p> <p>8 MS. AHERN: Objection. Form.</p> <p>9 THE WITNESS: You know, as -- this -- well, if</p> <p>10 they've been exposed to talc, by seeing evidence of it</p> <p>11 in the tissue, could essentially also mean superimposed</p> <p>12 particles on top of the tissue that could be there as a</p> <p>13 contaminant. So I'm not convinced.</p> <p>14 BY MR. DEARING:</p> <p>15 Q Okay. How would it have gotten there as a</p> <p>16 contaminant?</p> <p>17 A Because talc is all over the place.</p> <p>18 Q So you're talking about after it's removed</p> <p>19 from the body?</p> <p>20 A Yeah.</p> <p>21 Q Okay.</p> <p>22 A When you look at a pathology laboratory, the</p> <p>23 laboratory counters, the paper towels, the ceramics --</p> <p>24 Q Right.</p> <p>25 A -- it all contains talc.</p>
<p style="text-align: right;">Page 199</p> <p>1 They can be all wrong for all I know.</p> <p>2 Q Do you think they're all wrong?</p> <p>3 A I have -- I can't see it, and that's what</p> <p>4 you're asking me. Do I see it and believe it? I don't</p> <p>5 believe it.</p> <p>6 Q One of these authors, by the way, is William</p> <p>7 Welch that we talked about earlier.</p> <p>8 A We talked about him earlier.</p> <p>9 Q Do you think he's wrong?</p> <p>10 A Well, I don't even know what Bill's role was</p> <p>11 in this. He may have just said, "Oh, yeah. It was the</p> <p>12 lymph nodes with something in them."</p> <p>13 Q Is it your testimony today that these six</p> <p>14 authors looked at these photomicrographs and got it</p> <p>15 wrong --</p> <p>16 MS. AHERN: Objection.</p> <p>17 BY MR. DEARING:</p> <p>18 Q -- and then published it in a peer-reviewed</p> <p>19 journal?</p> <p>20 MS. AHERN: Objection. Form. That's not his</p> <p>21 testimony. He's already given you an answer to this</p> <p>22 question.</p> <p>23 THE WITNESS: They obviously believe it. I -- if</p> <p>24 you were -- in -- my opinion is they wrote it, but I</p> <p>25 don't see it.</p>	<p style="text-align: right;">Page 201</p> <p>1 Q Of course.</p> <p>2 A It could easily be introduced into the</p> <p>3 specimen.</p> <p>4 Q Sure. And is a macrophage going to engulf a</p> <p>5 talc particle that's been taken out of the body and is</p> <p>6 sitting on a lab or a paper towel?</p> <p>7 A As I said --</p> <p>8 MS. AHERN: Objection.</p> <p>9 THE WITNESS: -- I can't distinguish that this is</p> <p>10 in a macrophage. It may be talc particles sitting on</p> <p>11 top of the macrophage.</p> <p>12 BY MR. DEARING:</p> <p>13 Q Several times in response to my questions,</p> <p>14 you've answered with "I'm not convinced."</p> <p>15 Is that the burden that you're applying to</p> <p>16 your opinions in this case is that if you're not</p> <p>17 convinced, then it's not so?</p> <p>18 MS. AHERN: Objection. Form.</p> <p>19 THE WITNESS: I can only say what I believe in</p> <p>20 based on the scientific evidence. In this case, I'm</p> <p>21 not convinced that the talc particles or the</p> <p>22 birefringent particles that are being shown in these</p> <p>23 figures are actually within the tissue as a result of</p> <p>24 them actually being engulfed or whether they are there</p> <p>25 as a possible -- as a contaminant.</p>

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<p style="text-align: right;">Page 202</p> <p>1 BY MR. DEARING:</p> <p>2 Q Is that the standard that you're using for</p> <p>3 causation, that you're not convinced?</p> <p>4 MS. AHERN: Objection. Form. Misstates and</p> <p>5 mischaracterizes his testimony.</p> <p>6 MR. DEARING: I don't know what his testimony is.</p> <p>7 I'm asking him.</p> <p>8 THE WITNESS: I told you earlier what I expected to</p> <p>9 see in causation. And that was a fulfillment of all</p> <p>10 those criteria that we discussed at multiple times.</p> <p>11 BY MR. DEARING:</p> <p>12 Q Right. But the fulfillment of that criteria</p> <p>13 has to rise to a level of a preponderance of the</p> <p>14 evidence in court, and I want to know what standard</p> <p>15 you're applying.</p> <p>16 Is it until Dr. Kurman is convinced, or is it</p> <p>17 a preponderance of the evidence or something else?</p> <p>18 MS. AHERN: Objection. Form.</p> <p>19 THE WITNESS: A preponderance of the evidence, of</p> <p>20 course.</p> <p>21 BY MR. DEARING:</p> <p>22 Q Okay. So are you suggesting that applying the</p> <p>23 preponderance of the evidence to this study, that the</p> <p>24 preponderance of the evidence suggests these six</p> <p>25 authors got this wrong, that they're not observing talc</p>	<p style="text-align: right;">Page 204</p> <p>1 saying. I wondered what led them to do polarization of</p> <p>2 these lymph nodes if they saw nothing. You know, we</p> <p>3 routinely don't polarize tissues in surgical pathology,</p> <p>4 as even your expert acknowledged.</p> <p>5 So what led them to do -- to do polarization</p> <p>6 if there was no suspicion based on the H&amp;E slides?</p> <p>7 BY MR. DEARING:</p> <p>8 Q Right. Well, I'm not really asking you what</p> <p>9 you're wondering about. I'm just asking you if you saw</p> <p>10 any statements in there -- and I know you haven't read</p> <p>11 it word for word, but you spent about 15 minutes</p> <p>12 skimming over it.</p> <p>13 No mention of granulomatous giant cell</p> <p>14 response to talc particles, is there?</p> <p>15 MS. AHERN: Objection. Form. He hasn't reviewed</p> <p>16 the entire article.</p> <p>17 THE WITNESS: From what I read in this 15 minutes,</p> <p>18 I haven't seen that.</p> <p>19 BY MR. DEARING:</p> <p>20 Q Okay. I looked through your CV and tried to</p> <p>21 do a quick calculation. It looks like you've received</p> <p>22 somewhere in the neighborhood of \$6 million in funding</p> <p>23 from pharmaceutical companies for research in your</p> <p>24 career.</p> <p>25 Does that sound about accurate to you?</p>
<p style="text-align: right;">Page 203</p> <p>1 particles being engulfed by macrophages?</p> <p>2 MS. AHERN: Objection. Form. Argumentative.</p> <p>3 Misstates his testimony. He's already answered this</p> <p>4 question. This is the first time he's looking at this</p> <p>5 study. He hasn't reviewed the entire thing.</p> <p>6 MR. DEARING: He wasn't asked about preponderance</p> <p>7 of the evidence.</p> <p>8 MS. AHERN: He's told you what his basic opinion is</p> <p>9 from looking at the study in the last few minutes.</p> <p>10 That's his opinion.</p> <p>11 THE WITNESS: I'm even wondering how they just</p> <p>12 decide to look at this particular lymph node without</p> <p>13 mentioning that they saw some kind of funny reaction</p> <p>14 with the H&amp;E slides that then led them to do</p> <p>15 polarization. I didn't -- I can't find that.</p> <p>16 BY MR. DEARING:</p> <p>17 Q It's explained in there.</p> <p>18 A Well, maybe you can point it out to me. This</p> <p>19 is the first time I've seen the article.</p> <p>20 Q In the brief skimming through that that you</p> <p>21 just did and the portions that you read, there was no</p> <p>22 mention of granulomatous giant cell responses to talc</p> <p>23 particles, was there?</p> <p>24 MS. AHERN: Objection. Form.</p> <p>25 THE WITNESS: In my brief skimming, that's what I'm</p>	<p style="text-align: right;">Page 205</p> <p>1 MS. AHERN: Objection. Form.</p> <p>2 THE WITNESS: No. I would like to see that.</p> <p>3 BY MR. DEARING:</p> <p>4 Q Okay.</p> <p>5 A Which pharmaceutical companies?</p> <p>6 Q Look at your CV, if you like. It's under the</p> <p>7 title "Pharmaceutical Companies Supported." It looks</p> <p>8 like the Upjohn Company --</p> <p>9 A Wait a minute. Wait a minute. Wait a minute.</p> <p>10 MS. AHERN: I'm sorry. What page are you on,</p> <p>11 David, in the CV?</p> <p>12 THE WITNESS: I see it. It's page 58.</p> <p>13 MS. AHERN: Thank you.</p> <p>14 BY MR. DEARING:</p> <p>15 Q Okay. It looks like the Upjohn Company gave</p> <p>16 you 1.3 million and change for research.</p> <p>17 A Wait a minute. You're looking at line 1,</p> <p>18 right, Upjohn Company?</p> <p>19 Q I'm going through the whole thing.</p> <p>20 A I see 1993 to 1995. I see 314,540.</p> <p>21 Q Keep going. There are other entries for</p> <p>22 Upjohn.</p> <p>23 A Clinical at Wyeth Ayerst, '93 to '98, 59,000.</p> <p>24 Randomized clinical -- that's a -- an NCI</p> <p>25 study.</p>



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<p>1 Merck, human papillomavirus, '99 to '03,</p> <p>2 274,000.</p> <p>3 You know, in case you're not aware of it, this</p> <p>4 money doesn't go directly to me. It goes to the</p> <p>5 university.</p> <p>6 Q I know.</p> <p>7 A Okay. You know that.</p> <p>8 Q I'm just asking you --</p> <p>9 A Merck.</p> <p>10 Q -- you've received approximately \$6 million of</p> <p>11 funding for research in your career from pharmaceutical</p> <p>12 companies?</p> <p>13 A Upjohn --</p> <p>14 MS. AHERN: Objection.</p> <p>15 BY MR. DEARING:</p> <p>16 Q Upjohn, Merck, Watson, Wyeth, and Pfizer.</p> <p>17 A All going to Hopkins. I don't get money. I</p> <p>18 don't get paid that amount.</p> <p>19 Q Does that number sound about right, though?</p> <p>20 A Well, I haven't added them all up, so I'd have</p> <p>21 to sit here in -- with a calculator and add it all up.</p> <p>22 Q How much have you earned testifying for</p> <p>23 Johnson &amp; Johnson to date?</p> <p>24 A Since I was first approached?</p> <p>25 Q Yes.</p>	<p>1 it anymore or they were someone else's opinions, the</p> <p>2 other author's opinions.</p> <p>3 Are you saying you just -- you don't think</p> <p>4 it's necessary to inform the reader that you're --</p> <p>5 A Well, I'll have to think --</p> <p>6 Q -- a highly paid expert witness for Johnson &amp;</p> <p>7 Johnson?</p> <p>8 MS. AHERN: Objection. Form.</p> <p>9 THE WITNESS: I'll have to think that out and make</p> <p>10 a decision.</p> <p>11 BY MR. DEARING:</p> <p>12 Q Okay. Do you know whether the next</p> <p>13 Blaustein's edition includes the epidemiology studies,</p> <p>14 the 25 to 28 studies that show a statistically</p> <p>15 significant increased risk of ovarian cancer in women</p> <p>16 who use talc for feminine hygiene?</p> <p>17 MS. AHERN: Objection. Misstates the literature.</p> <p>18 THE WITNESS: We don't go into that degree of</p> <p>19 depth. It'll be a comment very similar -- maybe a</p> <p>20 little bit more elaborate than what we had in the 2011</p> <p>21 edition, but it's not going to -- it's not an</p> <p>22 epidemiological textbook. It's not going to go into</p> <p>23 all those details.</p> <p>24 BY MR. DEARING:</p> <p>25 Q As I just mentioned and as you've testified,</p>
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<p>1 A A little over \$190,000 since 2015.</p> <p>2 Q Okay. And you haven't billed for any of your</p> <p>3 preparation work for this deposition; right?</p> <p>4 MS. AHERN: Objection.</p> <p>5 THE WITNESS: No. That includes partial billing</p> <p>6 for this.</p> <p>7 BY MR. DEARING:</p> <p>8 Q Okay.</p> <p>9 A Not entirely, partial.</p> <p>10 Q And the next edition of Blaustein's that you</p> <p>11 said is on the way --</p> <p>12 A In press, yeah.</p> <p>13 Q -- in press --</p> <p>14 A Almost in press.</p> <p>15 Q -- are you going to disclose in there</p> <p>16 somewhere that you are a paid witness for Johnson &amp;</p> <p>17 Johnson in the talcum powder litigation?</p> <p>18 A I'll have to look at that. We don't --</p> <p>19 there's some comment about talc, just very similar to</p> <p>20 what we said there. I don't know that it influenced --</p> <p>21 it influenced my -- again, it's a statement of what's</p> <p>22 out there in the literature.</p> <p>23 Q Well, you are -- you've already said that you</p> <p>24 don't necessarily agree with some of the statements in</p> <p>25 this version, whether because you just don't agree with</p>	<p>1 you don't necessarily agree with all of the statements</p> <p>2 made by other authors in this textbook; right?</p> <p>3 A Right. As I said, the book is intended to</p> <p>4 give a general overview of what's out there. I may not</p> <p>5 necessarily specifically agree with something. But we</p> <p>6 felt, in fairness, it all needs to be discussed.</p> <p>7 Q Well, it's not all being discussed because</p> <p>8 you're not discussing both sides of these issues on</p> <p>9 everything; right?</p> <p>10 A What -- both sides of what issues? I mean --</p> <p>11 Q Well, for example, when we were talking</p> <p>12 earlier about -- I don't remember now.</p> <p>13 Oh, we were talking about whether chronic</p> <p>14 inflammation, nonasbestos mineral fibers may be</p> <p>15 etiologic agents for malignant mesothelioma --</p> <p>16 malignant -- perineal malignancies.</p> <p>17 And you said, well, that's one position, but</p> <p>18 you didn't offer the other position that those aren't</p> <p>19 etiologic agents for peritoneal.</p> <p>20 So would you agree with me that you've -- you</p> <p>21 haven't explained both sides of some of these topics?</p> <p>22 MS. AHERN: Objection. Form.</p> <p>23 THE WITNESS: Well, we've tried, to the best of our</p> <p>24 ability, to do so.</p> <p>25 ///</p>

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<p style="text-align: right;">Page 210</p> <p>1 BY MR. DEARING:</p> <p>2 Q Would you agree that good scientists can have</p> <p>3 differing opinions about cancer etiology?</p> <p>4 MS. AHERN: Objection. Form.</p> <p>5 THE WITNESS: That's a very, very general question.</p> <p>6 But if I frame it within the talc litigation, I would</p> <p>7 venture to say that a reasonable scientist viewing --</p> <p>8 viewing all -- viewing the totality of this data, I</p> <p>9 don't think anyone would agree to say that talc causes</p> <p>10 ovarian cancer.</p> <p>11 BY MR. DEARING:</p> <p>12 Q Are you saying that all of the plaintiffs'</p> <p>13 experts, the 30 or so plaintiff experts, that you know</p> <p>14 about, are not good scientists?</p> <p>15 MS. AHERN: Objection. Form.</p> <p>16 THE WITNESS: I didn't say that.</p> <p>17 BY MR. DEARING:</p> <p>18 Q Okay. Well, my question is, do you agree with</p> <p>19 me that good scientists can have differing opinions</p> <p>20 about cancer etiology?</p> <p>21 MS. AHERN: Objection. Form.</p> <p>22 THE WITNESS: It's neither good or bad. I'm saying</p> <p>23 that reasonable people looking at all this data, in my</p> <p>24 opinion, would not disagree that this is -- that talc</p> <p>25 causes ovarian cancer.</p>	<p style="text-align: right;">Page 212</p> <p>1 to review for publication that offered some type of</p> <p>2 cancer causation analysis that you thought was just</p> <p>3 biologically not plausible, implausible, would you</p> <p>4 still recommend that publication -- that study for</p> <p>5 publication?</p> <p>6 MS. AHERN: Objection. Form. Incomplete</p> <p>7 hypothetical. Other problems.</p> <p>8 THE WITNESS: I would ask the author to present</p> <p>9 more convincing evidence.</p> <p>10 BY MR. DEARING:</p> <p>11 Q Sure. So you wouldn't -- you wouldn't approve</p> <p>12 or recommend for publication a study that wasn't</p> <p>13 biologically plausible, right, in your mind?</p> <p>14 A I would like to see the data and the evidence</p> <p>15 that you're referring to, if there's a specific case</p> <p>16 for me to answer this very general question.</p> <p>17 Q I don't have a specific case. I'm asking you</p> <p>18 a general question.</p> <p>19 The general question is, if you were reviewing</p> <p>20 a study on some cause of cancer -- and I'm not even</p> <p>21 using a specific, any cause of cancer -- a cause of</p> <p>22 cancer that was being purported in a study and you felt</p> <p>23 like it wasn't biologically plausible, you would not</p> <p>24 recommend that paper for publication; right?</p> <p>25 MS. AHERN: Objection. Form.</p>
<p style="text-align: right;">Page 211</p> <p>1 BY MR. DEARING:</p> <p>2 Q Right. I'm not asking you about this data.</p> <p>3 I'm talking about cancer in general.</p> <p>4 For example, there are good scientists,</p> <p>5 reputable, knowledgeable scientists that disagree with</p> <p>6 you about your STIC theory; right?</p> <p>7 MS. AHERN: Objection. Form.</p> <p>8 THE WITNESS: Not many. Not this day and age.</p> <p>9 Even your expert agrees with us.</p> <p>10 BY MR. DEARING:</p> <p>11 Q I know. I'm not saying that. I'm saying</p> <p>12 there are scientists that don't agree with you.</p> <p>13 That doesn't make them bad scientists; right?</p> <p>14 A Didn't say they're bad scientists.</p> <p>15 Q Do you currently sit on any editorial boards</p> <p>16 or peer review panels?</p> <p>17 A I've taken my -- I retired from those.</p> <p>18 Q So, no, you're not currently on any?</p> <p>19 A No.</p> <p>20 Q When was the last time you sat on one?</p> <p>21 A Well, I -- when I retired in June of 2017, I</p> <p>22 withdrew from the various editorial boards that I was</p> <p>23 on -- that I was currently on.</p> <p>24 Q If you were sitting on a board -- editorial</p> <p>25 board or a peer review panel and you were given a study</p>	<p style="text-align: right;">Page 213</p> <p>1 THE WITNESS: I'd like to see the study that you're</p> <p>2 talking about.</p> <p>3 BY MR. DEARING:</p> <p>4 Q There is no study. I'm making it up.</p> <p>5 MS. AHERN: Objection.</p> <p>6 THE WITNESS: Well, I don't want to comment about</p> <p>7 things that you make up.</p> <p>8 BY MR. DEARING:</p> <p>9 Q Okay. So you don't have an opinion either way</p> <p>10 whether -- if you reviewed a study that was suggesting</p> <p>11 something that wasn't biologically plausible in your</p> <p>12 mind whether you'd approve it for publication?</p> <p>13 MS. AHERN: Objection. Form.</p> <p>14 THE WITNESS: You're making these hypothetical</p> <p>15 questions that, to me, are -- I can't answer that.</p> <p>16 BY MR. DEARING:</p> <p>17 Q You can't answer the simple question of</p> <p>18 whether a paper was sent to you to review that you felt</p> <p>19 offered some theory that was not biologically</p> <p>20 plausible, in your mind, whether you would recommend it</p> <p>21 for publication? You can't answer that question?</p> <p>22 MS. AHERN: Objection. Form. Asked and answered</p> <p>23 several times.</p> <p>24 THE WITNESS: No comment.</p> <p>25 ///</p>

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<p style="text-align: right;">Page 214</p> <p>1 BY MR. DEARING:</p> <p>2 Q I thought that was an easy question.</p> <p>3 All right. The second half of your report is</p> <p>4 a criticisms of Dr. Kane.</p> <p>5 Do you agree?</p> <p>6 A Yes.</p> <p>7 Q And were you hired by Johnson &amp; Johnson to</p> <p>8 offer criticisms of Dr. Kane?</p> <p>9 MS. AHERN: Object to the form.</p> <p>10 THE WITNESS: No.</p> <p>11 BY MR. DEARING:</p> <p>12 Q Were you offered by Johnson &amp; Johnson to offer</p> <p>13 your opinions about Dr. Kane's opinions?</p> <p>14 A I was asked --</p> <p>15 MS. AHERN: Objection. Form.</p> <p>16 THE WITNESS: -- to review Dr. Kane's report and</p> <p>17 comment on it.</p> <p>18 BY MR. DEARING:</p> <p>19 Q One of the first things you say in your</p> <p>20 comments section about Dr. Kane -- on page 12, you</p> <p>21 write, "Although Dr. Kane offers opinions in a host of</p> <p>22 areas outside her field, including epidemiology and</p> <p>23 cancer biology" --</p> <p>24 A I'm sorry. Where -- let's be on the same</p> <p>25 page.</p>	<p style="text-align: right;">Page 216</p> <p>1 Q In fact, your textbooks often lead with a</p> <p>2 section on epidemiology in every chapter almost, don't</p> <p>3 they?</p> <p>4 A I said that earlier. I said sure, we do that,</p> <p>5 but I'm not focusing in on an epidemiology review.</p> <p>6 Q Well, it's full of epidemiological data, isn't</p> <p>7 it?</p> <p>8 A Yes, yes, yes.</p> <p>9 Q Okay. And, in fact, in one of your previous</p> <p>10 editions, in the fifth edition, you actually have an</p> <p>11 entire chapter devoted to epidemiology, don't you?</p> <p>12 MS. AHERN: Objection. Form.</p> <p>13 THE WITNESS: You'll notice we removed that.</p> <p>14 BY MR. DEARING:</p> <p>15 Q Yeah. But you felt like it was important for</p> <p>16 pathologists to understand epidemiology, and that's why</p> <p>17 you put a chapter in this textbook; isn't it?</p> <p>18 MS. AHERN: Objection. Form.</p> <p>19 THE WITNESS: In the fifth edition. And then we</p> <p>20 included it in each section in the sixth edition.</p> <p>21 BY MR. DEARING:</p> <p>22 Q Right.</p> <p>23 A Of course, epidemiology is important.</p> <p>24 (The document referenced below was</p> <p>25 marked Deposition Exhibit 7 for</p>
<p style="text-align: right;">Page 215</p> <p>1 Right in the beginning. Okay. Go ahead.</p> <p>2 Q You suggest in the last sentence of the first</p> <p>3 paragraph that Dr. Kane is offering opinions in a host</p> <p>4 of areas outside her field, including epidemiology and</p> <p>5 cancer biology; right?</p> <p>6 A Yes.</p> <p>7 Q You would agree with me, wouldn't you, that a</p> <p>8 pathologist, a learned, skilled pathologist, has a</p> <p>9 working knowledge of epidemiology; right?</p> <p>10 A Working knowledge --</p> <p>11 MS. AHERN: Objection. Form.</p> <p>12 THE WITNESS: -- is different than expertise.</p> <p>13 BY MR. DEARING:</p> <p>14 Q I don't think she claimed to be an expert in</p> <p>15 epidemiology.</p> <p>16 A Well, Dr. Kane, in her report -- she's been</p> <p>17 asked to present pathology of ovarian cancer, as I</p> <p>18 understand it -- devotes exactly one paragraph to a</p> <p>19 discussion of ovarian cancer, which is less than a</p> <p>20 percent of her entire report, and spends nearly</p> <p>21 50 percent discussing epidemiology. Doesn't make sense</p> <p>22 to me.</p> <p>23 Q Well, you know how to read epidemiology</p> <p>24 studies, don't you?</p> <p>25 A Yeah.</p>	<p style="text-align: right;">Page 217</p> <p>1 identification and is appended hereto.)</p> <p>2 BY MR. DEARING:</p> <p>3 Q I'm going to show you what's marked as</p> <p>4 Exhibit 7, which is that chapter on epidemiology.</p> <p>5 MS. AHERN: Or a page from that chapter?</p> <p>6 MR. DEARING: The front page. That's the cover</p> <p>7 page from that chapter.</p> <p>8 MS. AHERN: From the fifth edition?</p> <p>9 MR. DEARING: The fifth edition.</p> <p>10 MS. AHERN: Okay. Exhibit 7. Do you have an extra</p> <p>11 copy? Okay. Thank you.</p> <p>12 BY MR. DEARING:</p> <p>13 Q And, as you can see, it's written by Dr. Mark</p> <p>14 Schiffman, and it's Chapter 27.</p> <p>15 A Yes.</p> <p>16 Q And then he leads that chapter -- hopefully,</p> <p>17 you can read that.</p> <p>18 A Well, I'm looking at your handout.</p> <p>19 Q Okay. Yeah, even this one's hard to read.</p> <p>20 I'm sorry. My daughter made that for me a couple days</p> <p>21 ago. It says:</p> <p>22 "Most pathologists are part-time</p> <p>23 epidemiologists as well. Two medical</p> <p>24 disciplines are more closely allied</p> <p>25 than" -- "the two medical disciplines</p>

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<p style="text-align: right;">Page 218</p> <p>1 are more closely allied than many people</p> <p>2 realize. Epidemiologists study the</p> <p>3 distribution and determinants of</p> <p>4 diseases in human populations. In</p> <p>5 current medical practices, diseases are</p> <p>6 often defined by histopathologic</p> <p>7 diagnoses or by clinical pathologic test</p> <p>8 values."</p> <p>9 Did I read that right?</p> <p>10 A You read that correct.</p> <p>11 Q And this is a chapter you actually edited;</p> <p>12 right?</p> <p>13 MS. AHERN: Objection. Form.</p> <p>14 THE WITNESS: The fifth edition, yes.</p> <p>15 BY MR. DEARING:</p> <p>16 Q Okay. So there's nothing necessarily</p> <p>17 inappropriate about a skilled, learned pathologist from</p> <p>18 discussing pathology -- I mean, epidemiology; right?</p> <p>19 A Of course. But the point is she's a</p> <p>20 pathologist and she spends over half -- nearly half her</p> <p>21 report on epidemiology and a paragraph on pathology.</p> <p>22 It doesn't seem right, even though we're part-time</p> <p>23 epidemiologists.</p> <p>24 Q You spent half of your report critiquing</p> <p>25 Dr. Kane. So I could suggest that's not right.</p>	<p style="text-align: right;">Page 220</p> <p>1 doing bench research and the pathologist who's doing</p> <p>2 surgical pathology. So, yes, of course, a surgical</p> <p>3 pathologist is going to be aware and understanding but</p> <p>4 is not going to have expertise necessarily in cancer</p> <p>5 biology.</p> <p>6 BY MR. DEARING:</p> <p>7 Q Well, pathologists have had training in cancer</p> <p>8 biology, haven't they?</p> <p>9 A Well, we read about it, we acquaint ourselves</p> <p>10 with it, we go to lectures, we know something about it,</p> <p>11 but we are not experts in it necessarily.</p> <p>12 Q And cancer pathology papers often discuss cell</p> <p>13 biology, don't they?</p> <p>14 A Yes.</p> <p>15 Q You go on to state that your primary area of</p> <p>16 expertise is gynecologic pathology.</p> <p>17 So tell me, what is your -- well, you've</p> <p>18 already explained to us what your methodology is. Do</p> <p>19 you have any criticism of Dr. Kane's methodology as far</p> <p>20 as her -- I know you disagree with some of her</p> <p>21 opinions, but do you have any criticism of the</p> <p>22 methodology she used to go about that?</p> <p>23 A Yes.</p> <p>24 Q Okay. Tell me what that criticism is.</p> <p>25 A Well, one of the main things to start with is</p>
<p style="text-align: right;">Page 219</p> <p>1 MS. AHERN: Objection.</p> <p>2 THE WITNESS: Well, that was in order to point out</p> <p>3 the shortcomings of her analysis. That's all that</p> <p>4 referred to.</p> <p>5 BY MR. DEARING:</p> <p>6 Q I just want to make sure it's crystal-clear</p> <p>7 that you're not suggesting skilled, experienced</p> <p>8 pathologists, like yourself and Dr. Kane, don't</p> <p>9 understand epidemiology.</p> <p>10 MS. AHERN: Objection. Form.</p> <p>11 THE WITNESS: I never said that.</p> <p>12 BY MR. DEARING:</p> <p>13 Q All right. And would you agree with me that</p> <p>14 you can't explain cancer pathology and etiology without</p> <p>15 some understanding and explanation of cancer biology?</p> <p>16 MS. AHERN: Objection. Form.</p> <p>17 THE WITNESS: Cancer biology and epidemiology all</p> <p>18 come into play.</p> <p>19 BY MR. DEARING:</p> <p>20 Q So skilled, experienced, learned pathologists</p> <p>21 typically do know quite a bit about cancer biology if</p> <p>22 they are studying cancer; right?</p> <p>23 MS. AHERN: Objection. Form.</p> <p>24 THE WITNESS: Well, again, there's a difference</p> <p>25 between a pathologist that's a molecular biologist</p>	<p style="text-align: right;">Page 221</p> <p>1 something we've been discussing during the entire</p> <p>2 course of this deposition, and that is that it's now</p> <p>3 generally accepted that high-grade serous carcinoma of</p> <p>4 the ovary begins in the fallopian tube with a precursor</p> <p>5 p53 signature, p53 STICs, and not the surface</p> <p>6 epithelium of the ovary. And she even admits that.</p> <p>7 But yet all the data that she cites, various biology,</p> <p>8 the cell cultures and studies that she refers, they're</p> <p>9 all dealing with the epithelial ovarian tissue, the</p> <p>10 surface epithelium of the ovary, which is not the</p> <p>11 precursor of ovarian cancer. So those are not valid.</p> <p>12 Q It sounds like you are disagreeing with her</p> <p>13 opinion as to the carcinogenesis of ovarian cancers if</p> <p>14 her opinion is they're starting in epithelial cells on</p> <p>15 the ovarian surface; right?</p> <p>16 MS. AHERN: Objection. Form.</p> <p>17 BY MR. DEARING:</p> <p>18 Q Is that what you're saying?</p> <p>19 MS. AHERN: Objection. Form.</p> <p>20 THE WITNESS: I'm disagreeing with the studies that</p> <p>21 she cites to support her opinion that talc causes</p> <p>22 ovarian cancer are based on studies in which she has</p> <p>23 not looked at the true precursor of high-grade serous</p> <p>24 carcinoma. That's what I'm saying.</p> <p>25 ///</p>

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<p style="text-align: right;">Page 222</p> <p>1 BY MR. DEARING:</p> <p>2 Q Sir, are you saying she's relying on faulty</p> <p>3 studies to reach her conclusions?</p> <p>4 A In -- the studies may not be faulty, just the</p> <p>5 wrong study. Well, as I've said, the precursors -- you</p> <p>6 need causation, initiation. We talked about this all</p> <p>7 morning. Should be looking at the precursor lesion in</p> <p>8 the organ where the lesion begins.</p> <p>9 She's looking at -- she's looking at the</p> <p>10 ovarian surface epithelium, or at least citing studies</p> <p>11 that evaluated the ovarian surface epithelium, which is</p> <p>12 not where these cancers begin. So, therefore, she has</p> <p>13 selected studies that are inappropriate.</p> <p>14 Q Do you have any other criticism of her</p> <p>15 methodology other than she's looked at --</p> <p>16 A Well, we can go through them if you want on</p> <p>17 every -- you know, one at a time.</p> <p>18 Q Let's just talk just generally with regard to</p> <p>19 methodology. And we can talk -- we will go</p> <p>20 individually.</p> <p>21 A Okay.</p> <p>22 Q But from just a general standpoint, you</p> <p>23 suggested one problem with her methodology is that</p> <p>24 she's looking at the wrong studies.</p> <p>25 A Right.</p>	<p style="text-align: right;">Page 224</p> <p>1 A Well, you want to begin with analogy? You</p> <p>2 just brought it up a minute ago.</p> <p>3 Q Sure.</p> <p>4 A Okay. I can read from my report.</p> <p>5 "Dr. Kane overstates the</p> <p>6 significance of compositional</p> <p>7 similarities between talc and asbestos.</p> <p>8 Specifically, Dr. Kane relies on an</p> <p>9 observed 'chemical similarity' between</p> <p>10 the two, but the two -- but the fact the</p> <p>11 two materials have similar chemical</p> <p>12 compositions does not mean they will</p> <p>13 have similar effects on the body. For</p> <p>14 instance, the chemical composition of</p> <p>15 water is almost identical to that of</p> <p>16 hydrogen peroxide -- they differ by only</p> <p>17 one oxygen atom -- but their biological</p> <p>18 effects are vastly different. Dr. Kane</p> <p>19 fails to provide any support for her</p> <p>20 suggestion that compositional</p> <p>21 similarities between talc and asbestos</p> <p>22 result in similar biologic effects.</p> <p>23 While talc and asbestos are both</p> <p>24 silicate minerals, talc is inert. By</p> <p>25 contrast, surface reactivity and the</p>
<p style="text-align: right;">Page 223</p> <p>1 Q Any other criticism of her methodology</p> <p>2 generally?</p> <p>3 A Some of the studies themselves may have issues</p> <p>4 with them specifically. But that, I think, is one of</p> <p>5 the main problems, if you're trying to present evidence</p> <p>6 for ovarian carcinogenesis and causation, to select the</p> <p>7 wrong tissues to be evaluated. Everything else goes by</p> <p>8 the wayside. If the first part doesn't make any sense</p> <p>9 biologically, then the rest is of no value.</p> <p>10 Q Okay. Let's start breaking it down issue by</p> <p>11 issue.</p> <p>12 One of the first issues you identify -- that</p> <p>13 you criticize is that Dr. Kane made observations</p> <p>14 regarding similarities between talc and asbestos and</p> <p>15 between high-grade serous carcinoma and mesothelioma.</p> <p>16 We've already discussed the Bradford Hill causation</p> <p>17 analysis to some extent.</p> <p>18 Do you agree with me that this -- that that</p> <p>19 analogy is also one of those nine considerations of</p> <p>20 Bradford Hill; right?</p> <p>21 A Yes. Analogy is, yes.</p> <p>22 Q So with regard to Dr. Kane looking at the</p> <p>23 wrong studies and your criticism of her methodology, is</p> <p>24 there anything else that comes to mind with regard to</p> <p>25 her methodology that you think is inappropriate?</p>	<p style="text-align: right;">Page 225</p> <p>1 ability to release free radicals</p> <p>2 contribute to the pathogenic effects of</p> <p>3 asbestos."</p> <p>4 Do you want me to go on?</p> <p>5 Q Can you I stop you there? No, I don't. I</p> <p>6 just didn't want to cut you off midsentence.</p> <p>7 A Okay.</p> <p>8 Q I know what your report says. I want to ask</p> <p>9 you some questions about it.</p> <p>10 A Okay.</p> <p>11 Q So your criticism of her application of</p> <p>12 analogy --</p> <p>13 A Right.</p> <p>14 Q -- the one of nine Bradford Hill</p> <p>15 considerations --</p> <p>16 A Right.</p> <p>17 Q -- you think that's a methodology flaw?</p> <p>18 A Yes. And also, even -- you didn't want me to</p> <p>19 go on, but the next is that the analogy between</p> <p>20 malignant mesothelioma --</p> <p>21 Q I'll get to that.</p> <p>22 A -- and -- okay.</p> <p>23 Q You agree with me that Dr. Kane is not saying</p> <p>24 that talc and asbestos are morphologically identical;</p> <p>25 right?</p>

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<p style="text-align: right;">Page 226</p> <p>1 A She makes that comment at some point, but then</p> <p>2 she says they're similar.</p> <p>3 Q She doesn't say they're identical, does she?</p> <p>4 A She may not, but she builds her whole case of</p> <p>5 analogy on the fact that they're doing the same thing.</p> <p>6 Q I think you testified already, you haven't</p> <p>7 look at talc fibers under a microscope, have you?</p> <p>8 A I have not.</p> <p>9 Q So you don't know whether asbestiform talc</p> <p>10 fibers and asbestos fibers are similar; right?</p> <p>11 MS. AHERN: Objection. Form.</p> <p>12 BY MR. DEARING:</p> <p>13 Q Similar in morphology.</p> <p>14 MS. AHERN: Objection. Form.</p> <p>15 THE WITNESS: I'm referring to what is easily</p> <p>16 available in the literature, even for a layman who's</p> <p>17 not a mineralogist --</p> <p>18 BY MR. DEARING:</p> <p>19 Q Okay.</p> <p>20 A -- that talc and asbestos are very different</p> <p>21 from a structural standpoint. Structure is more</p> <p>22 important, in fact, than chemistry in causing</p> <p>23 biological effects.</p> <p>24 Q I'm not talking about chemistry. I'm talking</p> <p>25 about morphology.</p>	<p style="text-align: right;">Page 228</p> <p>1 making this analogy comparison.</p> <p>2 MS. GARBER: This is a speaking objection.</p> <p>3 MR. DEARING: Thank you. You don't need to do</p> <p>4 that.</p> <p>5 MS. AHERN: Well, it was, I think, appropriate</p> <p>6 under the circumstances. You are talking past each</p> <p>7 other.</p> <p>8 MS. GARBER: It's not appropriate under CMO 11.</p> <p>9 You've been doing it all day. You should stop because</p> <p>10 you're breaking the rules.</p> <p>11 BY MR. DEARING:</p> <p>12 Q You don't discuss fibrous talc in your report?</p> <p>13 A That's right.</p> <p>14 Q Is that why you're looking at your report?</p> <p>15 A I'm looking at my report, yeah.</p> <p>16 Q Okay. So do you have an answer to that</p> <p>17 question?</p> <p>18 A My answer is that talc, as the -- as is</p> <p>19 reported in the literature, has been indicated in</p> <p>20 virtually every study to be different than asbestos.</p> <p>21 Q It is different.</p> <p>22 A I'm not getting into asbestiform or any of</p> <p>23 that stuff.</p> <p>24 Q Okay. I don't know if you know the answer to</p> <p>25 this question, but when a scientist is using the</p>
<p style="text-align: right;">Page 227</p> <p>1 A Right.</p> <p>2 Q They're both needle-like fibers. So they're</p> <p>3 similar.</p> <p>4 A No, they're not.</p> <p>5 Q They're not similar at all?</p> <p>6 A No.</p> <p>7 Q Okay. We already talked about the fact that</p> <p>8 IARC treats asbestos fibers and asbestiform fibrous</p> <p>9 talc the same with regard to the carcinogenicity</p> <p>10 evaluation; right?</p> <p>11 MS. AHERN: Objection. Form.</p> <p>12 THE WITNESS: Again, there's a lot of confusion in</p> <p>13 this terminology, and I don't want to get stuck into</p> <p>14 that.</p> <p>15 BY MR. DEARING:</p> <p>16 Q I'm not confused.</p> <p>17 A You're better than I am.</p> <p>18 Q Well, I don't want to confuse you. So let me</p> <p>19 put it out there again. Maybe you just don't know, but</p> <p>20 do you know whether IARC has classified fibrous talc,</p> <p>21 specifically asbestiform fibrous talc, as carcinogenic</p> <p>22 as it did asbestos fibers?</p> <p>23 MS. AHERN: Objection. Asked and answered. And I</p> <p>24 think this is supposed to be about Dr. Kane's report,</p> <p>25 and she doesn't mention asbestiform talc when she's</p>	<p style="text-align: right;">Page 229</p> <p>1 Bradford Hill assessment to determine causal</p> <p>2 association and that scientist is studying analogy, you</p> <p>3 agree that analogy doesn't mean that the -- the agents</p> <p>4 are identical, but what it means is that they are --</p> <p>5 they have reasonable demonstrable similarities; right?</p> <p>6 Do you know that or --</p> <p>7 A I'm aware of that, but I don't believe they</p> <p>8 have reasonable demonstrable similarities.</p> <p>9 Q Fair enough.</p> <p>10 Do you agree that both fibrous talc and</p> <p>11 asbestos are both fibrous silicate minerals that cannot</p> <p>12 be readily absorbed or dissolved by the body?</p> <p>13 MS. AHERN: Objection. Form.</p> <p>14 THE WITNESS: Talc cannot be easily absorbed and</p> <p>15 degraded. Asbestos, on the other hand, can penetrate</p> <p>16 tissues and stay in there for periods of time and get</p> <p>17 into small areas that can lead to development of</p> <p>18 mesothelioma.</p> <p>19 BY MR. DEARING:</p> <p>20 Q And they both elicit a biomechanistic</p> <p>21 foreign-body response in the body; right?</p> <p>22 MS. AHERN: Objection. Form.</p> <p>23 THE WITNESS: Again, I'm not aware of asbestos</p> <p>24 producing a foreign-body giant cell granulomatous</p> <p>25 reaction. It produces fibrosis.</p>

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<p style="text-align: right;">Page 230</p> <p>1 BY MR. DEARING:</p> <p>2 Q You use the analogy of water and hydrogen</p> <p>3 peroxide as two things that may look similar that are</p> <p>4 very different.</p> <p>5 Did you come up with that yourself? Because</p> <p>6 it's actually been used in two opening statements in</p> <p>7 trials.</p> <p>8 MS. AHERN: Objection. Form.</p> <p>9 THE WITNESS: Honestly, I have another suggest --</p> <p>10 it was actually brought up by counsel, and I totally</p> <p>11 agreed with it. But I actually had other comparisons</p> <p>12 that I could have mentioned, which I didn't.</p> <p>13 BY MR. DEARING:</p> <p>14 Q You go on to say in your report that talc</p> <p>15 particles are normally plate-like, unlike asbestos</p> <p>16 fibers. And I assume you read that somewhere; right?</p> <p>17 A Yeah, probably in the IARC monograph.</p> <p>18 Q But you make no mention of fibrous talc. Do</p> <p>19 you know that fibrous talc exists?</p> <p>20 MS. AHERN: Objection. Form.</p> <p>21 THE WITNESS: I've already commented on the</p> <p>22 business of fibrous talc. I'm not going to get into</p> <p>23 it.</p> <p>24 BY MR. DEARING:</p> <p>25 Q I just want to know if you knew about it.</p>	<p style="text-align: right;">Page 232</p> <p>1 Q It says:</p> <p>2 "In any event, although it is well</p> <p>3 established that asbestos exposure can</p> <p>4 cause pleural mesothelioma (and much</p> <p>5 less commonly lung cancer), the data</p> <p>6 implicating asbestos exposure and</p> <p>7 ovarian cancer is significantly weaker."</p> <p>8 When you make that statement about ovarian</p> <p>9 cancer, you're referring to epidemiological data,</p> <p>10 right, when you say "data"?</p> <p>11 A Pretty much so, yes.</p> <p>12 Q So you criticize Dr. Kane for discussing</p> <p>13 epidemiology, and then you rely on an epidemiological</p> <p>14 study for -- to support your criticism; right?</p> <p>15 A Well, in order to criticize her</p> <p>16 epidemiological studies, I had to use epidemiological</p> <p>17 studies.</p> <p>18 Q Okay. But you agree that, as we've already</p> <p>19 seen, the data implicating asbestos exposure and</p> <p>20 ovarian cancer was strong enough for IARC to make that</p> <p>21 connection; right?</p> <p>22 MS. AHERN: Objection. Form.</p> <p>23 THE WITNESS: We've discussed this earlier, and I</p> <p>24 mentioned the various -- what I felt are shortcomings</p> <p>25 of that analysis, and it's summarized here. Especially</p>
<p style="text-align: right;">Page 231</p> <p>1 A Sure, sure.</p> <p>2 Q All I'm asking is if you know whether it</p> <p>3 exist.</p> <p>4 A I've known it. I've seen it mentioned. Yeah,</p> <p>5 sure.</p> <p>6 Q So you know about it; you just didn't feel the</p> <p>7 need to mention it in your report?</p> <p>8 MS. AHERN: Objection. Form.</p> <p>9 THE WITNESS: Well, I didn't want to go into all</p> <p>10 those details because I didn't feel that it was</p> <p>11 necessary. I thought there was sufficient evidence to</p> <p>12 indicate that talc, as described in the literature, is</p> <p>13 different from asbestos described in the literature</p> <p>14 insofar as the biological effects that the two produce.</p> <p>15 BY MR. DEARING:</p> <p>16 Q In your report on page 14, you state "In any</p> <p>17 event, although it is well established that" --</p> <p>18 A Wait, wait, wait. I see Dr. Kane's claim.</p> <p>19 Are we worried about that? Where are we?</p> <p>20 Q Right. It's about -- one, two, three, four --</p> <p>21 five lines down from the top, starting "in any event."</p> <p>22 A Oh. Top photograph.</p> <p>23 Q Right.</p> <p>24 A One, two, three four -- "in any event." Okay.</p> <p>25 Go ahead.</p>	<p style="text-align: right;">Page 233</p> <p>1 when you're comparing it to perineal exposure of talc,</p> <p>2 we're talking about inhalation studies, we're talking</p> <p>3 about very high occupational exposures or environmental</p> <p>4 exposures which are very high. The number of women in</p> <p>5 these studies is very small, and there's a significant</p> <p>6 chance that these tumors were not carcinomas but</p> <p>7 mesotheliomas.</p> <p>8 BY MR. DEARING:</p> <p>9 Q So several times you keep saying occupational</p> <p>10 exposure and that exposure was very high. But if you</p> <p>11 don't believe asbestos can cause ovarian cancer, why</p> <p>12 does it matter how high the exposure is?</p> <p>13 A Well, certain thresholds are required for</p> <p>14 certain things.</p> <p>15 Q Do you think if there's enough ovarian</p> <p>16 exposure to asbestos, that it might cause ovarian</p> <p>17 cancer?</p> <p>18 A I'm saying that's maybe why they came to that</p> <p>19 conclusion. They're looking at huge exposures. And,</p> <p>20 yeah, that may be very significant as opposed to a very</p> <p>21 minimal exposure.</p> <p>22 Q Of course, when Dr. Kane made the observation</p> <p>23 that high-grade serous carcinoma and mesothelioma have</p> <p>24 striking morphologic similarities, she also referred to</p> <p>25 two studies that suggest the same thing; right?</p>

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<p style="text-align: right;">Page 234</p> <p>1 A I'd have to look at her report, what those two 2 studies are. 3 Q I actually don't have her report. I'm sorry. 4 A I can't comment. 5 Q Well, would you agree with me that high-grade 6 serous carcinoma and mesothelioma, although not 7 identical, they do have significant morphologic 8 similarities? 9 MS. AHERN: Objection. Form. 10 THE WITNESS: Lots of tumors have similar 11 morphologic similarities. 12 BY MR. DEARING: 13 Q Well, those two are so close that pathologists 14 might have mistaken one for the other for years before 15 histopathologic stains were improved eight years ago. 16 A I think, if you weren't an expert in 17 gynecologic pathology, that may have been -- that may 18 have been an issue. 19 Q So are you agreeing me that they're 20 pathologically similar enough to where experienced 21 surgical pathologists may have been diagnosing ovarian 22 cancer when it was mesothelioma or vice versa? 23 A No. You said -- I said experienced 24 pathologists probably would not have that problem. 25 Inexperienced pathologists might have that problem.</p>	<p style="text-align: right;">Page 236</p> <p>1 pathologists that are referred to in these studies were 2 inexperienced? 3 A One of the studies that they're describing, 4 they describe using the Danish Cancer Registry, and I 5 have, in fact, done studies with the Danish Cancer 6 Registry. And they report a certain disagreement. I 7 think I came up with 16 percent or something like that. 8 And I said, well, maybe it could even be as high as 9 20 percent. 10 Well, you have to understand how these 11 registry studies are done, at least in Denmark where I 12 have direct personal experience. These -- the data 13 that comes in are from every hospital throughout the 14 country of Denmark, and it's based on pathology 15 records, for the most part. 16 When we did our studies of ovarian tumors, 17 borderline tumors, we requested that the slides be sent 18 in. And they probably did something like that in one 19 of those studies. And I can tell you that in our 20 studies, looking at those cases that had been 21 classified -- I'm talking about the borderline 22 studies -- there was significant disagreement because 23 those pathologists weren't that skilled. They just 24 didn't see enough of these rather uncommon cases to 25 make the correct diagnosis.</p>
<p style="text-align: right;">Page 235</p> <p>1 Q Well, let's quote it exactly, on page 14. You 2 state in the last sentence or so of the first paragraph 3 "Finally, from a pathology standpoint" -- 4 A Wait, wait. I don't see -- where's "finally"? 5 Q Last sentence, Doctor. You're way below it. 6 First paragraph. 7 A Oh, the first paragraph. 8 Q Top paragraph. 9 A "Finally." I see it. 10 Q Okay. 11 "Finally, from a pathology 12 standpoint, there is a significant 13 likelihood that some tumors observed in 14 these occupational studies, which are 15 quite dated, were misclassified due to 16 misreporting on death certificates and 17 lack of immunohistochemical analysis to 18 adequately distinguish peritoneal 19 mesothelioma from ovarian cancer (i.e., 20 peritoneal mesotheliomas were 21 misdiagnosed as ovarian carcinomas)." 22 So by acknowledging that the pathologists may 23 have misdiagnosed those tumors but then saying but not 24 an experienced -- an experienced pathologist wouldn't 25 make that mistake, are you saying that all the</p>	<p style="text-align: right;">Page 237</p> <p>1 And I suspect a similar thing may have 2 happened with these mesotheliomas. Mesotheliomas are 3 relatively uncommon. Little hospitals throughout 4 Denmark may be seeing one mesothelioma, you know, every 5 five years. So they don't have that much experience. 6 So they may have misclassified them. They may be 7 higher than the 16 percent that they refer to. 8 That's what I was getting at. 9 Q So the bottom line is you're speculating that 10 some of these pathologists may have misdiagnosed 11 mesotheliomas for ovarian carcinomas? 12 MS. AHERN: Objection. Form. 13 THE WITNESS: I'm basing it on my own experience. 14 Not with mesothelioma, but with the Danish tumor 15 registry, with cases seen by nonexpert pathologists 16 sending in to a central review that there is -- there 17 was misclassification, yes. 18 BY MR. DEARING: 19 Q So this is a court proceeding, and in court 20 we're interested in evidence. And do you have any 21 evidence that these pathologists in this study that 22 you're referring to likely misdiagnosed ovarian 23 carcinomas for mesotheliomas? 24 MS. AHERN: Objection. Form. 25 THE WITNESS: I said there's a significant</p>

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<p>1 possibility. I didn't say likelihood.</p> <p>2 BY MR. DEARING:</p> <p>3 Q What are you basing that on other than -- you</p> <p>4 said -- well, you're basing that on your experience</p> <p>5 with Denmark?</p> <p>6 A Well, I can -- yes, my experience with Denmark</p> <p>7 and the Danish tumor registry.</p> <p>8 Q Okay. Would you agree with me that the fact</p> <p>9 that skilled surgical pathologists might be confusing</p> <p>10 ovarian cancers with mesothelial cancers or</p> <p>11 mesotheliomas, it suggests that those cancers are</p> <p>12 sufficiently similar to meet the analogy consideration</p> <p>13 of Bradford Hill?</p> <p>14 MS. AHERN: Objection. Form.</p> <p>15 THE WITNESS: As I said, a skilled gynecologic</p> <p>16 pathologist, I don't think, would make that mistake. I</p> <p>17 think some of those misclassifications are due to</p> <p>18 nonskilled pathologists who don't see that much. And,</p> <p>19 therefore, mesothelioma and -- malignant mesothelioma</p> <p>20 and high-grade serous carcinoma can be distinguished</p> <p>21 morphologically and aided also with immunized</p> <p>22 chemistry.</p> <p>23 BY MR. DEARING:</p> <p>24 Q Sure. I'm not saying they can't be</p> <p>25 distinguished. They clearly can be. My question is</p>	<p>1 Last sentence of the first paragraph.</p> <p>2 A Yes.</p> <p>3 Q Actually, that's not it. Wait a minute.</p> <p>4 On the next page, second sentence, page 16.</p> <p>5 You say, "Foreign-body granulomas are what you would</p> <p>6 expect to find in tissue exposed to noninfectious</p> <p>7 material like talc and surgical gloves"; right?</p> <p>8 A Sutures.</p> <p>9 Q I'm sorry, surgical sutures.</p> <p>10 And for support of that statement, you cite to</p> <p>11 a study by Dr. Kabeer Shah in the Journal of Clinical</p> <p>12 Tuberculosis and Other Mycobacterial Diseases; right?</p> <p>13 A Let me see. That's 108. That doesn't seem to</p> <p>14 be the right reference. Hmm. Oh, 106. Sorry. No,</p> <p>15 106 doesn't seem to be correct either.</p> <p>16 Am I looking at the wrong part?</p> <p>17 Shah here. It should be 95, the reference.</p> <p>18 MS. AHERN: I think he's referring to your</p> <p>19 footnote.</p> <p>20 THE WITNESS: Could you please repeat your question</p> <p>21 and tell me what you're referring to exactly.</p> <p>22 BY MR. DEARING:</p> <p>23 Q Sure. With regard to your statement,</p> <p>24 "Foreign-body granulomas are what you would expect to</p> <p>25 find in tissue exposed to noninfectious material like</p>
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<p>1 the fact that these surgeons were confusing them for</p> <p>2 years, apparently, doesn't that rise to the level of</p> <p>3 analogy for purposes of a Bradford Hill causal</p> <p>4 association analysis?</p> <p>5 MS. AHERN: Objection. Form.</p> <p>6 THE WITNESS: You mean pathologists, not surgeons.</p> <p>7 Pathologists.</p> <p>8 BY MR. DEARING:</p> <p>9 Q Pathologists, right.</p> <p>10 A I don't think it rises to the level necessary</p> <p>11 to really prove that there's analogy.</p> <p>12 Q You also take exception to Dr. Kane's</p> <p>13 recitation of the evidence that talc-induced chronic</p> <p>14 inflammation can cause ovarian cancer; right?</p> <p>15 A Are we on a specific page of my report or her</p> <p>16 report?</p> <p>17 Q Sure. It's just the next section.</p> <p>18 "Talc-induced chronic inflammation is a cause of</p> <p>19 ovarian cancer."</p> <p>20 A Okay. All right. Okay.</p> <p>21 Q We've already had a lengthy conversation about</p> <p>22 foreign-body granulomas and foreign-body responses.</p> <p>23 A Right.</p> <p>24 Q But for support -- well, first, you say</p> <p>25 "foreign-body granuloma" -- I'm sorry.</p>	<p>1 talc and surgical sutures," and you say footnote 108 to</p> <p>2 support that statement; right?</p> <p>3 A Shah, yes.</p> <p>4 Q Right. You go down to footnote 108, that's</p> <p>5 the Shah study?</p> <p>6 A Right.</p> <p>7 Q Okay. I'm handing you the Shah study that I</p> <p>8 believe you're referring to.</p> <p>9 MR. DEARING: Anybody else want a copy?</p> <p>10 I'm going to mark it as Exhibit Number 8.</p> <p>11 MS. AHERN: Thank you.</p> <p>12 MR. DEARING: Will you give him the marked one so</p> <p>13 we can be proper about this.</p> <p>14 MS. AHERN: Yeah.</p> <p>15 (The document referenced below was</p> <p>16 marked Deposition Exhibit 8 for</p> <p>17 identification and is appended hereto.)</p> <p>18 BY MR. DEARING:</p> <p>19 Q Is that the study that you relied on for that</p> <p>20 statement?</p> <p>21 A Yes.</p> <p>22 Q And this study is entitled "Histopathologic</p> <p>23 Review of Granulomatous Inflammation"; right?</p> <p>24 A Yes.</p> <p>25 Q And Dr. Shah does suggest granulomatous</p>

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<p style="text-align: right;">Page 242</p> <p>1 inflammation might be associated with talc, surgical 2 sutures, and food material? 3 A Are you reading something specifically that I 4 should be looking at? 5 Q Well, sure. On page 3 -- 6 A Okay. 7 Q -- about a little over midway down the 8 left-hand column -- 9 A All right. 10 Q -- it starts "Two broad forms." 11 A Yes. 12 Q And we talked about these already. 13 A Right. 14 Q "Two broad forms of well-defined granuloma 15 exist, defined by their etiology." There's that word 16 again. 17 Do you know how he is using the word 18 "etiology" in that sentence? 19 A Yeah. He's dividing them into those that are 20 foreign-body giant cell granulomas and immune 21 granulomas. That's all I can make out of it. 22 Q So -- okay. And he says, "Foreign-body giant 23 cells are histiocytic reactions to otherwise inert 24 material without an adaptive immune response, for 25 example, suture, talc, and food material"; right?</p>	<p style="text-align: right;">Page 244</p> <p>1 MS. AHERN: Objection. Form. 2 BY MR. DEARING: 3 Q And in your years of experience, you've never 4 observed -- well, let me ask you, have you ever 5 observed a surgical suture in gynecologic -- 6 A Oh, yes. 7 Q -- material? 8 A Yeah. 9 Q And did they form granulomatous reactions -- 10 A Yes. 11 Q -- or granulomas? 12 A Yes. 13 Q You can actually see surgical sutures and 14 granulomas with the naked eye, can't you? 15 A You can actually see them with the naked eye, 16 that's right. 17 Q That's because surgical sutures are quite 18 large compared to talc particles, aren't they? 19 MS. AHERN: Objection. Form. 20 BY MR. DEARING: 21 Q Well, let me ask you -- 22 THE WITNESS: I would think so, yes. 23 BY MR. DEARING: 24 Q Based on Dr. McDonald's study we've already 25 looked at --</p>
<p style="text-align: right;">Page 243</p> <p>1 A Yep. 2 Q "A collection of histiocytes 3 surround the foreign material and as 4 single histiocytes are unable to 5 phagocytize the foreign material alone. 6 The foreign material" -- I'm sorry. 7 "The foreign material can be visualized 8 by light microscopy and often exhibits 9 birefringence using polarized light." 10 So histiocytes are macrophages; right? 11 A Right. 12 Q Okay. So what he's saying there is that these 13 giant cells form when macrophages alone cannot engulf 14 the particle; right? 15 A Well, when a single, I think, macrophage 16 can't, so they join forces to encompass this larger 17 material. 18 Q So when the material is too big for a single 19 macrophage to phagocytize -- which means to ingest; 20 right? 21 A Right. 22 Q So if the particle is too big for the 23 macrophage to ingest alone, more macrophages join in, 24 and then a giant cell granuloma is formed; right? 25 A Correct.</p>	<p style="text-align: right;">Page 245</p> <p>1 A Right. 2 Q If the average size of a talc particle in 3 gynecologic tissue that they've studied is in the 5- to 4 10-micron range, a typical surgical suture is probably 5 a thousand times larger than that; right? 6 A Sure, it's larger. Sure. 7 Q Not just larger, a thousand times larger? 8 MS. AHERN: Objection. Form. 9 THE WITNESS: I don't know if it's a thousand or 10 500 or 200 or what. Larger. 11 BY MR. DEARING: 12 Q Well, by reference, would you agree that a 13 human hair is about 80 to 100 microns in diameter? 14 A I honestly have never measured. I don't know. 15 Q Does that seem unreasonable? I looked it up. 16 A You looked it up. I haven't looked it up, so 17 I don't -- 18 Q Okay. 19 A Since I'm under oath, I don't want to say 20 something that may not be true. 21 Q Okay. Well, I'm just trying to add context to 22 what a micron is in size. 23 So we're talking about granulomatous responses 24 to surgical sutures that are -- if -- if talc particles 25 and tissue are 5 microns, surgical sutures are probably</p>



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<p style="text-align: right;">Page 246</p> <p>1 a thousand times bigger than a talc particle; right?</p> <p>2 MS. AHERN: Objection. Form.</p> <p>3 THE WITNESS: We didn't agree on your -- the</p> <p>4 decision that they're a thousand times -- but they're</p> <p>5 larger. Let's put it that way.</p> <p>6 BY MR. DEARING:</p> <p>7 Q Well, you can't see a 5-micron talc particle</p> <p>8 with the naked eye, can you?</p> <p>9 A No.</p> <p>10 Q But you can see a surgical suture with the</p> <p>11 naked eye?</p> <p>12 A Yeah. But I can't extrapolate from that that</p> <p>13 it's a thousand times larger. That's all I'm saying.</p> <p>14 Q Right. It's probably bigger than that, but</p> <p>15 the point is made.</p> <p>16 So when Dr. Shah suggested talc might elicit a</p> <p>17 granulomatous response, he's referring to very large</p> <p>18 talc particles, not small 5-micron particles or large</p> <p>19 clusters of particles; right?</p> <p>20 MS. AHERN: Objection. Form.</p> <p>21 BY MR. DEARING:</p> <p>22 Q Do you not have an answer to that?</p> <p>23 A Oh, I'm sorry. I missed it. What was your</p> <p>24 question?</p> <p>25 Q So when Dr. Shah is suggesting that talc might</p>	<p style="text-align: right;">Page 248</p> <p>1 in this study?</p> <p>2 MS. AHERN: Objection. Form.</p> <p>3 THE WITNESS: As I recall --</p> <p>4 BY MR. DEARING:</p> <p>5 Q Or any gynecologic tissue, for that matter?</p> <p>6 A Not specifically.</p> <p>7 MS. AHERN: Objection. Form.</p> <p>8 BY MR. DEARING:</p> <p>9 Q When he discusses reactions to talc, he's</p> <p>10 referring to lung tissue that has trapped large talc</p> <p>11 particles or clusters of particles by either inhalation</p> <p>12 or surgical pleurodesis; right?</p> <p>13 MS. AHERN: Objection. Where are you reading from?</p> <p>14 In the Shah article?</p> <p>15 MR. DEARING: Yeah.</p> <p>16 BY MR. DEARING:</p> <p>17 Q In the beginning, he describes the organs that</p> <p>18 he's considering.</p> <p>19 MS. AHERN: I'm sorry. The abstract?</p> <p>20 MR. DEARING: Maybe.</p> <p>21 BY MR. DEARING:</p> <p>22 Q Yeah. "The pulmonary system is one of the</p> <p>23 most commonly affected sites to encounter granulomatous</p> <p>24 inflammation."</p> <p>25 A Okay.</p>
<p style="text-align: right;">Page 247</p> <p>1 elicit a granulomatous response, he's referring to very</p> <p>2 large talc particles, like industrial grade, not</p> <p>3 cosmetic-grade particles that are 5 microns?</p> <p>4 MS. AHERN: Okay.</p> <p>5 BY MR. DEARING:</p> <p>6 Q Or large clusters of particles, he might be</p> <p>7 referring to those?</p> <p>8 MS. AHERN: Objection. Form.</p> <p>9 THE WITNESS: Yeah. I mean, I don't see why</p> <p>10 cosmetic talc can't clump together and form larger</p> <p>11 particles.</p> <p>12 BY MR. DEARING:</p> <p>13 Q And, again, the statement that you're using</p> <p>14 the study to support is that foreign-body granulomas</p> <p>15 are what you would expect to find in tissue exposed to</p> <p>16 noninfectious material like talc and surgical sutures.</p> <p>17 You are talking about gynecologic tissue</p> <p>18 exposed to talc, right --</p> <p>19 A Yeah.</p> <p>20 Q -- when you make that statement?</p> <p>21 MS. AHERN: Objection. Form.</p> <p>22 THE WITNESS: Sure.</p> <p>23 BY MR. DEARING:</p> <p>24 Q Okay. Dr. Shah never once mentions talc and</p> <p>25 granulomatous inflammation in ovarian tissue, does he,</p>	<p style="text-align: right;">Page 249</p> <p>1 Q Okay. But the point is he doesn't talk about</p> <p>2 any gynecologic tissue in his response to talc in this</p> <p>3 study; right?</p> <p>4 A I guess it's because it's so rare.</p> <p>5 Q Well, you're using a study to support the</p> <p>6 statement that foreign-body granulomas will form in</p> <p>7 gynecologic tissue if they're exposed to talc.</p> <p>8 A Right.</p> <p>9 Q And you're using a study that doesn't even</p> <p>10 discuss gynecologic tissue; right?</p> <p>11 A There's no reason for me to think that there</p> <p>12 would be a difference, but --</p> <p>13 Q Okay.</p> <p>14 A -- he didn't describe it, GYN.</p> <p>15 Q Okay. Look on page 5, if you would. And</p> <p>16 that's a photomicrograph. And the way Dr. Shah</p> <p>17 describes it is first he identifies a foreign-body</p> <p>18 giant cell reaction within the lung alveoli, and then</p> <p>19 he says, "with macrophages engulfing inhaled talc."</p> <p>20 A Okay.</p> <p>21 Q So what he's saying there is that it's</p> <p>22 actually macrophages engulfing talc particles, right,</p> <p>23 not --</p> <p>24 A We just said that before. Macrophages are</p> <p>25 equivalent to histiocytes.</p>

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<p>1 Q Right. But my point is he includes a</p> <p>2 photomicrograph of that happening just like</p> <p>3 Dr. McDonald, Godleski, Welch, that group did in that</p> <p>4 study that we went over a little while ago; right?</p> <p>5 MS. AHERN: Objection. Form. Mischaracterizes the</p> <p>6 paper.</p> <p>7 THE WITNESS: Perhaps so.</p> <p>8 BY MR. DEARING:</p> <p>9 Q Can you tell from looking at this</p> <p>10 photomicrograph whether talc particles are being</p> <p>11 engulfed by macrophages?</p> <p>12 A On the H&amp;E slide, I can see it, yes.</p> <p>13 Q So you believe that that's being accurately</p> <p>14 described?</p> <p>15 A I can see it, yes. I couldn't see it in that</p> <p>16 other paper.</p> <p>17 Q Okay. So on page 20 of your report, you</p> <p>18 criticize Dr. Kane for discussing parts of the body</p> <p>19 that is unrelated to ovarian carcinogenesis, yet --</p> <p>20 A What are you referring to now? What</p> <p>21 paragraph?</p> <p>22 Q Anyway -- and if I'm remembering this wrong,</p> <p>23 feel free to correct me; it's your report. But I seem</p> <p>24 to recall that you were criticizing Dr. Kane for using</p> <p>25 studies that didn't pertain to gynecologic tissue, they</p>	<p>1 presumably those of Dr. McDonald's study as well,</p> <p>2 macrophages can adequately sequester smaller talc</p> <p>3 particles; right?</p> <p>4 A Well, yeah. And they present that in the</p> <p>5 article. These are foreign-body granulomas that you're</p> <p>6 seeing here. These collections of -- all of them</p> <p>7 together form a foreign-body granuloma.</p> <p>8 Q But they're described as macrophages.</p> <p>9 A Yeah, but the macrophages form the granuloma.</p> <p>10 Q Only when they connect; right?</p> <p>11 A No, when they lump together.</p> <p>12 Q Right.</p> <p>13 A You can see it says "foreign-body giant cell</p> <p>14 reaction within long alveoli with macrophages engulfing</p> <p>15 inhaled talc."</p> <p>16 So the macrophages inhale the talc or</p> <p>17 phagocytize it. And as they come together, they form a</p> <p>18 foreign-body giant cell.</p> <p>19 MS. GARBEN: I'm just going to object to Ms. Ahern</p> <p>20 pointing out to the doctor where to look during his</p> <p>21 testimony. I request that she stop doing that. It's</p> <p>22 also violating the rules.</p> <p>23 MS. AHERN: Well, he's asking about that. I just</p> <p>24 simply pointed him to what he was asking him about.</p> <p>25 MS. GARBEN: You pointed him to where he needed to</p>
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<p>1 weren't gynecology studies, to support one of her</p> <p>2 propositions.</p> <p>3 Do you remember criticizing her for that?</p> <p>4 MS. AHERN: Objection. Form.</p> <p>5 THE WITNESS: I know you're having a problem, but</p> <p>6 I -- that came up different places, so I'd like to see</p> <p>7 exactly where you're referring so that I can try to</p> <p>8 respond.</p> <p>9 BY MR. DEARING:</p> <p>10 Q Well, tell you what. If I have time, I'll</p> <p>11 come back to that.</p> <p>12 A Okay.</p> <p>13 Q It's not that important.</p> <p>14 A Okay.</p> <p>15 Q The fact is many pathologists who have studied</p> <p>16 talc particles in tissue have recognized macrophages as</p> <p>17 the foreign-body response in talc particles, not large</p> <p>18 cell or giant cell granulomas; right?</p> <p>19 MS. AHERN: Objection. Form.</p> <p>20 THE WITNESS: No. The macrophages form giant</p> <p>21 cell --</p> <p>22 BY MR. DEARING:</p> <p>23 Q Right.</p> <p>24 A -- foreign-body giant cells.</p> <p>25 Q But as evidenced in these photomicrographs and</p>	<p>1 look to answer the question, so please stop doing that.</p> <p>2 MS. AHERN: Well, the question was misleading. I'm</p> <p>3 trying to assume that macrophages are different from</p> <p>4 foreign-body reaction.</p> <p>5 MR. DEARING: Okay. Well, make an objection.</p> <p>6 Don't coach the witness. Okay. Just make an</p> <p>7 objection. That's what you're supposed to do.</p> <p>8 MS. AHERN: Well, stop asking misleading questions.</p> <p>9 BY MR. DEARING:</p> <p>10 Q The same pathologists that have reported</p> <p>11 observing macrophages responding to talc particles in</p> <p>12 tissue also suggest that the reason giant cell</p> <p>13 granulomas are not formed is because the talc particles</p> <p>14 are too small and the macrophages can adequately</p> <p>15 sequester them.</p> <p>16 Do you agree with that position?</p> <p>17 MS. AHERN: Objection. Form.</p> <p>18 THE WITNESS: Please show me the reference that</p> <p>19 you're making.</p> <p>20 BY MR. DEARING:</p> <p>21 Q You haven't read any studies that you can</p> <p>22 recall that say that?</p> <p>23 A No, not specifically.</p> <p>24 Q Okay. While we're on the topic of</p> <p>25 macrophages, would you agree with me that macrophages</p>

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<p>1 can also release reactive oxygen species and reactive</p> <p>2 nitrogen species when they deteriorate?</p> <p>3 MS. AHERN: Objection. Form.</p> <p>4 THE WITNESS: Yes, they can.</p> <p>5 BY MR. DEARING:</p> <p>6 Q Have you taught medical students as part of</p> <p>7 your career?</p> <p>8 A Yes.</p> <p>9 Q What did you teach medical students with</p> <p>10 regard to whether size of foreign particles in any way</p> <p>11 determines the type of foreign-body reaction to it?</p> <p>12 MS. AHERN: Objection. Form.</p> <p>13 THE WITNESS: I don't think I ever taught them</p> <p>14 anything about that.</p> <p>15 BY MR. DEARING:</p> <p>16 Q Well, you certainly taught them about</p> <p>17 macrophages and giant cell granulomas; right?</p> <p>18 MS. AHERN: Objection. Form.</p> <p>19 THE WITNESS: Actually, I don't think I did.</p> <p>20 BY MR. DEARING:</p> <p>21 Q Okay. Something else you wrote in Blaustein's</p> <p>22 fourth edition --</p> <p>23 Tell you what. Can we take about a</p> <p>24 five-minute break?</p> <p>25 THE WITNESS: Sure.</p>	<p>1 starts "Rarely."</p> <p>2 Do you see that?</p> <p>3 A Yeah. Uh-huh.</p> <p>4 Q It says:</p> <p>5 "Rarely talc or another foreign</p> <p>6 substance may elicit a foreign-body</p> <p>7 reaction in the endometrium. Talc may</p> <p>8 be introduced into the endometrial</p> <p>9 cavity by instruments contaminated with</p> <p>10 talc powder or by gloves during a pelvic</p> <p>11 exam. Patients may be asymptomatic or</p> <p>12 may have menorrhagia."</p> <p>13 Did I pronounce that right?</p> <p>14 A Uh-huh.</p> <p>15 Q "Microscopically, the extent of</p> <p>16 the granulomatous inflammatory reaction</p> <p>17 depends on the quantity of the talc</p> <p>18 inoculated. The infiltrate is</p> <p>19 characterized by histiocytes and</p> <p>20 foreign-body multinucleated giant cells</p> <p>21 surrounding the talc crystals along with</p> <p>22 lymphocytes and plasma cells. The</p> <p>23 crystals appear as refractile,</p> <p>24 birefringent, needle-like, or fan-shaped</p> <p>25 splinters in polarizing light."</p>
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<p>1 VIDEO OPERATOR BROWN: Time is now 4:05. Going off</p> <p>2 the record.</p> <p>3 (Recess taken.)</p> <p>4 VIDEO OPERATOR BROWN: Okay. Time is now 4:20.</p> <p>5 Back on the record.</p> <p>6 (The document referenced below was</p> <p>7 marked Deposition Exhibit 9 for</p> <p>8 identification and is appended hereto.)</p> <p>9 BY MR. DEARING:</p> <p>10 Q Doctor, I'm showing you a portion of</p> <p>11 Blaustein's Pathology of the Female Genital Tract,</p> <p>12 Fourth Edition, marked as Exhibit Number 9.</p> <p>13 Actually, I'm sorry. Can I see that one</p> <p>14 again. Want to make sure I'm giving you the right one.</p> <p>15 I'm not.</p> <p>16 MS. AHERN: Thank you.</p> <p>17 BY MR. DEARING:</p> <p>18 Q And, Doctor, this is an excerpt from</p> <p>19 Chapter 14. It's entitled "Diseases of the Fallopian</p> <p>20 Tube," and it looks like it was authored by you and</p> <p>21 Dr. Mazur; is that right?</p> <p>22 A It looks that way, yes.</p> <p>23 Q Okay. What I want to point out is, on</p> <p>24 page 376, at the bottom, there's a paragraph that --</p> <p>25 well, almost at the bottom, there's a paragraph that</p>	<p>1 So two things I want to draw out of that</p> <p>2 paragraph.</p> <p>3 The first is, you say, "Microscopically, the</p> <p>4 extent of the granulomatous inflammatory reaction</p> <p>5 depends on the quantity of the talc inoculated."</p> <p>6 So what you're saying there, right, is that</p> <p>7 the type of foreign-body reaction the body exerts</p> <p>8 towards talc depends on how much talc is there or the</p> <p>9 size of the particles; right?</p> <p>10 MS. AHERN: Objection. Form.</p> <p>11 THE WITNESS: Not the type, the extent.</p> <p>12 BY MR. DEARING:</p> <p>13 Q By "extent," you mean?</p> <p>14 A Amount.</p> <p>15 Q Okay. So if there were just a few particles,</p> <p>16 three or four isolated particles, you know, that</p> <p>17 weren't right adjacent to each other that were in the</p> <p>18 5-micron range or so, would you expect that a</p> <p>19 macrophage could handle those?</p> <p>20 A I cannot -- you know, I can't get down into</p> <p>21 the specifics of the size. It would be more --</p> <p>22 basically, what that sentence means is the more of the</p> <p>23 inoculum, the more of an infiltrate you'll get. I</p> <p>24 can't break it down to, you know, three macrophages</p> <p>25 versus ten, whatever.</p>

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<p>1 Q Okay. But the extent of the granulomatous</p> <p>2 response depends on the quantity of the talc present in</p> <p>3 the tissue; right?</p> <p>4 A Right.</p> <p>5 Q The other thing I wanted to draw out of that</p> <p>6 is that the -- when you say, "The crystals appear as</p> <p>7 refractile, birefringent, needle-like, or fan-shaped</p> <p>8 splinters in polarizing light," you're talking about</p> <p>9 talc crystals; right?</p> <p>10 A Yes.</p> <p>11 Q So if they're needle-like, are you referring</p> <p>12 to talc fibers?</p> <p>13 MS. AHERN: Objection. Form.</p> <p>14 THE WITNESS: Talc.</p> <p>15 BY MR. DEARING:</p> <p>16 Q So you're acknowledging that talc can have</p> <p>17 needle-like morphology?</p> <p>18 A Yeah.</p> <p>19 MS. AHERN: Objection. Form.</p> <p>20 THE WITNESS: Yes.</p> <p>21 BY MR. DEARING:</p> <p>22 Q By the way, while we're on it, the fourth</p> <p>23 edition of Blaustein's -- and I don't have the book,</p> <p>24 but it actually identifies talc as a risk factor for</p> <p>25 ovarian cancer; doesn't it?</p>	<p>1 A Are you asking for the specific risk factors</p> <p>2 of ovarian cancer or just in general?</p> <p>3 Q In general, what do you mean by "risk</p> <p>4 factors," the term?</p> <p>5 A A factor that increases the risk of someone</p> <p>6 developing cancer.</p> <p>7 Q What are the recognized risk factors for</p> <p>8 ovarian cancer?</p> <p>9 MS. AHERN: Objection. Form.</p> <p>10 THE WITNESS: Well, it's a little bit of a</p> <p>11 complicated question in that different people have</p> <p>12 different opinions as to does -- is there enough data</p> <p>13 to suggest that this particular factor rises to the</p> <p>14 level of a risk factor. Some say, "Oh, yes, it does."</p> <p>15 Others say, "Well, it isn't."</p> <p>16 So there are these associations which some</p> <p>17 like to consider risk factors and some that don't.</p> <p>18 Some are much stronger than others.</p> <p>19 BY MR. DEARING:</p> <p>20 Q Can you specifically identify what you think</p> <p>21 are maybe the three strongest risk factors for ovarian</p> <p>22 cancer?</p> <p>23 A Well, family history, I think, is a strong</p> <p>24 one. I think genetic history in terms of specifically</p> <p>25 BRCA mutations is a very strong one. And I think kind</p>
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<p>1 A As a what, risk factor?</p> <p>2 Q For ovarian cancer.</p> <p>3 MS. AHERN: Objection. Form. Is there a question?</p> <p>4 MR. DEARING: Yes.</p> <p>5 THE WITNESS: Oh, you were asking me to comment on</p> <p>6 that?</p> <p>7 MR. DEARING: Let me ask it again.</p> <p>8 MS. AHERN: Actually, let him ask you a question</p> <p>9 first.</p> <p>10 THE WITNESS: Sorry. Yeah, I thought you were</p> <p>11 telling me.</p> <p>12 BY MR. DEARING:</p> <p>13 Q I did, and then I put a question mark on the</p> <p>14 end.</p> <p>15 So do you agree with me that the fourth</p> <p>16 edition identifies talc as a risk factor for ovarian</p> <p>17 cancer?</p> <p>18 A Well, again, I don't have the book, but I'd</p> <p>19 like to see what I said.</p> <p>20 Q You don't recall?</p> <p>21 A I don't remember. The fourth edition goes</p> <p>22 back a few years.</p> <p>23 Q Each of your Blaustein's has a chapter on risk</p> <p>24 factors for ovarian cancer.</p> <p>25 What are risk factors?</p>	<p>1 of a negative risk factor would be the use of birth</p> <p>2 control pills.</p> <p>3 Q By "negative," you mean a protective factor?</p> <p>4 A Protective factor, right.</p> <p>5 Q One of the statements you make in your report</p> <p>6 is that you mention talc pleurodesis, and I was just</p> <p>7 looking to try to find it and I don't see it. But I</p> <p>8 think you will recognize the statement. It said:</p> <p>9 "Further, if the consequence of</p> <p>10 talc and asbestos exposure were similar,</p> <p>11 one would expect to find cancer arising</p> <p>12 in patients who underwent talc</p> <p>13 pleurodesis."</p> <p>14 Remember, that was when you were criticizing</p> <p>15 her use of analogy of talc and asbestos and high-grade</p> <p>16 serous carcinoma and mesothelioma in the beginning.</p> <p>17 A Yes.</p> <p>18 Q My question is: Would you agree with me that</p> <p>19 talc pleurodesis is typically used to treat malignant</p> <p>20 pleural effusion and, more often, it's used in</p> <p>21 end-stage disease?</p> <p>22 MS. AHERN: Object to the form.</p> <p>23 THE WITNESS: Well, it's also treated in benign</p> <p>24 disease. It is also used in benign diseases.</p> <p>25 ///</p>

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<p style="text-align: right;">Page 262</p> <p>1 BY MR. DEARING:</p> <p>2 Q I understand. But the overwhelming majority</p> <p>3 of pleurodesis procedures are used in malignant</p> <p>4 end-stage diseases?</p> <p>5 MS. AHERN: Objection. Form.</p> <p>6 THE WITNESS: It is certainly used in malignant</p> <p>7 conditions, but I don't know about the overwhelming</p> <p>8 majority of them.</p> <p>9 BY MR. DEARING:</p> <p>10 Q Would you agree that the pleurodesis patients</p> <p>11 who are getting pleurodesis because of an end-stage</p> <p>12 malignancy typically don't live long enough to study</p> <p>13 the long-term effects of the talc pleurodesis on them?</p> <p>14 A That's probably true.</p> <p>15 Q And also the talc used in talc pleurodesis is</p> <p>16 a different grade of purity than the talc used in body</p> <p>17 powders; right?</p> <p>18 MS. AHERN: Objection. Form.</p> <p>19 THE WITNESS: Again, I wasn't going to get into the</p> <p>20 issue of how much is in there and what the purity is</p> <p>21 and all that. I defer to a mineralogist.</p> <p>22 BY MR. DEARING:</p> <p>23 Q And, typically, a pleurodesis procedure is</p> <p>24 a -- is a one-time administration of a heavy volume of</p> <p>25 talc as opposed to a slow trickle of chronic exposure;</p>	<p style="text-align: right;">Page 264</p> <p>1 (The document referenced below was</p> <p>2 marked Deposition Exhibit 10 for</p> <p>3 identification and is appended hereto.)</p> <p>4 BY MR. DEARING:</p> <p>5 Q This is publication in the ATS -- in the</p> <p>6 American Journal of Respiratory and Critical Care</p> <p>7 Medicine by Dr. Ghio and Victor Roggli.</p> <p>8 Do you know Dr. Roggli?</p> <p>9 A No, I don't.</p> <p>10 Q Well, Dr. Roggli is a pathologist and</p> <p>11 microscopist who has spent a career studying asbestos</p> <p>12 and mesothelioma and particularly quantifying asbestos</p> <p>13 burden in lung tissue.</p> <p>14 Does that sound familiar? You haven't heard</p> <p>15 about him?</p> <p>16 A I don't know him, no.</p> <p>17 Q Okay. Well, do you agree with me that the</p> <p>18 next-to-the-last sentence -- I'm sorry, I -- mean the</p> <p>19 last sentence of the first paragraph reads -- well, the</p> <p>20 title -- the title of this paper is "Talc Should Not Be</p> <p>21 Used for Pleurodesis in Patients with Nonmalignant</p> <p>22 Pleural Effusions." And Drs. Ghio and Roggli state</p> <p>23 that:</p> <p>24 "This dilemma results from a</p> <p>25 possible increased risk of malignant</p>
<p style="text-align: right;">Page 263</p> <p>1 right?</p> <p>2 MS. AHERN: Objection. Form.</p> <p>3 THE WITNESS: Heavy volume, yes. A lot it is put</p> <p>4 in there.</p> <p>5 BY MR. DEARING:</p> <p>6 Q It's actually talc slurry that's introduced</p> <p>7 into the pleural cavity; right?</p> <p>8 MS. AHERN: Objection. Form.</p> <p>9 THE WITNESS: Yes, that's correct.</p> <p>10 BY MR. DEARING:</p> <p>11 Q Do you agree with me that there are scientists</p> <p>12 and physicians that advise against using talc for</p> <p>13 pleurodesis with patients with nonmalignant pleural</p> <p>14 effusions?</p> <p>15 MS. AHERN: Objection. Form.</p> <p>16 THE WITNESS: I've read that there's a controversy,</p> <p>17 some saying it shouldn't be done and some say it's no</p> <p>18 problem.</p> <p>19 BY MR. DEARING:</p> <p>20 Q You think that the split is about 50-50, those</p> <p>21 in favor and those who warn against it?</p> <p>22 A Can't tell. I don't know what the split is.</p> <p>23 Q I brought one with me. Since I brought it, I</p> <p>24 might as well show it to you. Right? Actually, I</p> <p>25 brought two with me.</p>	<p style="text-align: right;">Page 265</p> <p>1 mesothelioma in those patients treated</p> <p>2 with talc. Consequently, an alternative</p> <p>3 agent should be employed in any</p> <p>4 additional" -- I'm sorry -- "in any</p> <p>5 individual without malignancy requiring</p> <p>6 pleurodesis."</p> <p>7 Then he also cites a reference of case reports</p> <p>8 of malignant mesothelioma after occupational exposure</p> <p>9 to talc would suggest a possible -- a potential</p> <p>10 association.</p> <p>11 So do you agree with me that, at least</p> <p>12 according to this paper, Drs. Ghio and Dr. Roggli</p> <p>13 advise against using talc for pleurodesis in patients</p> <p>14 with nonmalignant plural effusions?</p> <p>15 MS. AHERN: Objection. Form.</p> <p>16 THE WITNESS: Well, that's what they say. They do</p> <p>17 say that the dilemma is -- in this last two sentences</p> <p>18 above the first paragraph, they say the dilemma about</p> <p>19 using it for nonmalignant pleural effusions results</p> <p>20 from a possible increased risk of malignant</p> <p>21 mesothelioma in those patients treated with talc.</p> <p>22 BY MR. DEARING:</p> <p>23 Q Right. In other words --</p> <p>24 A Possible.</p> <p>25 Q Right. So he is saying there's a possibility</p>

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<p style="text-align: right;">Page 266</p> <p>1 that talc could cause lung cancers; right?</p> <p>2 A Mesotheliomas. I'm sorry. Malignant</p> <p>3 mesothelioma. We should distinguish carcinoma from</p> <p>4 mesothelioma.</p> <p>5 Q All right.</p> <p>6 A He says that at the end. And I do believe --</p> <p>7 I think -- I'd have to double-check, but I think there</p> <p>8 was a letter to the editor from someone who had written</p> <p>9 extensively on pleurodesis who said -- oh, it's Light.</p> <p>10 Yeah, Light. References Number 2, Light, RW.</p> <p>11 Do you see that one --</p> <p>12 Q Yes.</p> <p>13 A -- in his list of references?</p> <p>14 Well, there's a letter to the editor by Light</p> <p>15 who says I don't agree with that, that they shouldn't</p> <p>16 be using talc for pleurodesis in patients with</p> <p>17 malignant conditions -- nonmalignant conditions because</p> <p>18 there's never been a reported case of mesothelioma in</p> <p>19 patients with benign diseases treated with pleurodesis.</p> <p>20 Q Light --</p> <p>21 A And Light has written a lot of that as well.</p> <p>22 Q Right. Doesn't his paper say talc should not</p> <p>23 be used for pleurodesis in that cite?</p> <p>24 A No, I thought he --</p> <p>25 Q Look at Light cite Number 2.</p>	<p style="text-align: right;">Page 268</p> <p>1 A First paragraph. Okay.</p> <p>2 Q Second sentence.</p> <p>3 A Second sentence. Okay. "She has produced a</p> <p>4 lengthy report"?</p> <p>5 Q I'm sorry. Third sentence. "Dr. Kane opines</p> <p>6 that" --</p> <p>7 A "That" -- okay.</p> <p>8 Q -- "genital talcum powder exposure can cause</p> <p>9 ovarian cancer based on her evaluation of</p> <p>10 epidemiological, pathological, biological, and</p> <p>11 mechanistic evidence."</p> <p>12 Is it your testimony that there is no</p> <p>13 pathological, biological, and mechanistic evidence to</p> <p>14 support the assertion that talc exposure can cause</p> <p>15 ovarian cancer?</p> <p>16 MS. AHERN: Objection. Form.</p> <p>17 THE WITNESS: That's correct. I haven't seen that</p> <p>18 evidence.</p> <p>19 BY MR. DEARING:</p> <p>20 Q Further down in the third paragraph, about</p> <p>21 halfway, it says:</p> <p>22 "Dr. Kane does not identify any</p> <p>23 studies linking the use of talc-based</p> <p>24 body powders to the known genetic</p> <p>25 alterations associated with the various</p>
<p style="text-align: right;">Page 267</p> <p>1 A I think maybe it's an issue, but he -- and</p> <p>2 very specifically -- did we -- I thought I put that in</p> <p>3 there. I'd have -- I'd have to look for the reference.</p> <p>4 Q Okay.</p> <p>5 A But I definitely remember a letter to the</p> <p>6 editor responding to this saying I have never seen it;</p> <p>7 it's never been reported in the literature; so I would</p> <p>8 disagree with the fact that it shouldn't -- that</p> <p>9 pleurodesis with talc should not be used. I'll be able</p> <p>10 to find it.</p> <p>11 Q You also have a section in your report about</p> <p>12 precursor lesions. Here it is, page 6.</p> <p>13 A Page 6 of my report.</p> <p>14 Q Right. I'm sorry. If would you turn to</p> <p>15 page 12.</p> <p>16 A 12.</p> <p>17 Q 12.</p> <p>18 A Okay.</p> <p>19 Q In the first paragraph, second sentence, you</p> <p>20 state, "Dr. Kane opines that genital talcum powder</p> <p>21 exposure can cause ovarian cancer based on her</p> <p>22 evaluation of epidemiological" --</p> <p>23 A Wait, wait, wait. You said the second</p> <p>24 paragraph.</p> <p>25 Q I'm sorry. The first paragraph.</p>	<p style="text-align: right;">Page 269</p> <p>1 histologic subtypes of ovarian cancer.</p> <p>2 And, indeed, I am aware of no such</p> <p>3 studies."</p> <p>4 Would you agree me that many of the</p> <p>5 epidemiologic studies do assess or analyze the data or</p> <p>6 divide the data based on exposure and different</p> <p>7 histological subtypes of ovarian cancer?</p> <p>8 MS. AHERN: Objection. Form.</p> <p>9 THE WITNESS: They do, and they're pretty</p> <p>10 inconsistent, yes.</p> <p>11 BY MR. DEARING:</p> <p>12 Q And when you say "I'm aware of no such</p> <p>13 studies," are you referring to studies that demonstrate</p> <p>14 genetic alterations of cells exposed to talc?</p> <p>15 MS. AHERN: Objection. Form.</p> <p>16 THE WITNESS: I'm saying that there are certain</p> <p>17 genetic alterations that are involved with the -- with</p> <p>18 carcinogenesis of the different types -- high-grade</p> <p>19 serous, low-grade and endometrial clear cell -- and I'm</p> <p>20 not aware of any studies and she did not -- and</p> <p>21 Dr. Kane didn't mention them either -- linking talc</p> <p>22 powders to inducing those genetic alterations.</p> <p>23 (The document referenced below was</p> <p>24 marked Deposition Exhibit 11 for</p> <p>25 identification and is appended hereto.)</p>

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<p style="text-align: right;">Page 270</p> <p>1 BY MR. DEARING:</p> <p>2 Q I'm showing what is marked as Exhibit</p> <p>3 Number 11, and this is a study by Drs. Fletcher,</p> <p>4 Harper, Memaj, Fan, Morris, and Saed. I don't believe</p> <p>5 this study was identified in either of your reference</p> <p>6 lists.</p> <p>7 Do you know if you've ever seen this study?</p> <p>8 A No, I don't remember seeing this study.</p> <p>9 Q Well, title of this study is "Molecular Basis</p> <p>10 Supporting the Association of Talcum Powder Use with</p> <p>11 Increased Risk of Ovarian Cancer."</p> <p>12 A Yes.</p> <p>13 Q If you would, take a minute and look at the</p> <p>14 abstract. The last sentence of the abstract reads:</p> <p>15 "These findings are the first to</p> <p>16 confirm the cellular effect of talc and</p> <p>17 provide a molecular mechanism to</p> <p>18 previous reports linking genital talc</p> <p>19 use to increased ovarian cancer risk."</p> <p>20 A I was sort of reading the rest of the</p> <p>21 abstract. Let me go over it.</p> <p>22 Okay. I'm sorry, what was your question?</p> <p>23 Q Well, having read the abstract, do you feel</p> <p>24 like you have a good handle on the general topic of</p> <p>25 this study?</p>	<p style="text-align: right;">Page 272</p> <p>1 MS. AHERN: Objection. Form.</p> <p>2 BY MR. DEARING:</p> <p>3 Q For example, cigarette smoke can cause several</p> <p>4 times of cancer; right?</p> <p>5 MS. AHERN: Objection. Form.</p> <p>6 THE WITNESS: Lung cancer, sure. Yeah. What else?</p> <p>7 BY MR. DEARING:</p> <p>8 Q It can cause -- it has been linked to liver</p> <p>9 cancer; right?</p> <p>10 A I'm not familiar with that.</p> <p>11 Q Well, asbestos can cause mesothelioma and it</p> <p>12 can cause lung cancer; right?</p> <p>13 A It's usually not a significant cause of lung</p> <p>14 cancer. It's a contributing factor to people who are</p> <p>15 smokers.</p> <p>16 Q Asbestos is?</p> <p>17 A Yeah.</p> <p>18 Q Okay. Well, I know it usually causes</p> <p>19 mesothelioma, but asbestos can cause lung cancer;</p> <p>20 right?</p> <p>21 MS. AHERN: Objection. Form. Asked and answered.</p> <p>22 THE WITNESS: I think it's pretty rare. I think</p> <p>23 it's mostly, as I said, predominantly lung cancer and</p> <p>24 these -- they can add another factor to it, asbestos,</p> <p>25 what I've read about it, because I'm not an expert in</p>
<p style="text-align: right;">Page 271</p> <p>1 A Not at all.</p> <p>2 MS. AHERN: Objection. Form.</p> <p>3 BY MR. DEARING:</p> <p>4 Q Not at all?</p> <p>5 A No. I'd like to see the materials and</p> <p>6 methods. I'd like that see what they were actually</p> <p>7 studying. I was looking for that. I couldn't see</p> <p>8 that.</p> <p>9 Q You know, if you're not familiar with it,</p> <p>10 let's move on.</p> <p>11 A I'm not.</p> <p>12 Q I want to ask you what you're familiar with.</p> <p>13 I might come back to it if I have time for it.</p> <p>14 A Okay.</p> <p>15 Q Back to page 12.</p> <p>16 A Yes.</p> <p>17 Q Middle paragraph, last two sentences, you</p> <p>18 state:</p> <p>19 "Further, it is unlikely that</p> <p>20 exposure to a single agent, i.e., talc,</p> <p>21 could result in the development of such</p> <p>22 distinctly different neoplasms."</p> <p>23 My question is there are examples where a</p> <p>24 single etiologic agent can cause more than one type of</p> <p>25 cancer; right?</p>	<p style="text-align: right;">Page 273</p> <p>1 cigarette smoking and lung cancer.</p> <p>2 BY MR. DEARING:</p> <p>3 Q On page 20 you have a subheading "Detection of</p> <p>4 Talc in Ovarian Tissue."</p> <p>5 A I see it.</p> <p>6 Q And this appears to be a criticism of</p> <p>7 Dr. Kane's recitation of the evidence that talc has</p> <p>8 been observed in ovarian tissue and other gynecologic</p> <p>9 tissue.</p> <p>10 Is that an accurate summary?</p> <p>11 A Yes, uh-huh.</p> <p>12 Q Are you saying that that's just not true, that</p> <p>13 talc has not been observed in gynecologic tissue?</p> <p>14 A No. I think in my second sentence, I say,</p> <p>15 "She then acknowledges that the presence of talc</p> <p>16 particles found in ovarian cancer tissue does not prove</p> <p>17 that the talc played a causal role yet argues it is</p> <p>18 'consistent with causation and provides additional</p> <p>19 evidence in support after causal relationship,'" which</p> <p>20 is -- the whole sentence doesn't make sense to me.</p> <p>21 Q Okay. I just want to be clear. You're not</p> <p>22 taking exception to the fact that she's acknowledging</p> <p>23 that scientists have observed talc particles in ovarian</p> <p>24 tissue and other gynecologic tissue?</p> <p>25 A Well, in ovarian tissue, for sure.</p>

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<p style="text-align: right;">Page 274</p> <p>1 Q Are you saying the presence of talc in ovarian 2 tissue has no relevance to the issue of inflammation or 3 ovarian cancer? 4 A I'm saying it's not evidence that it's causing 5 ovarian cancer. 6 Q So you -- have you seen studies that identify 7 talc in ovarian tissue? 8 A Yes. 9 Q And in those same studies, did they identify a 10 granulomatous or giant cell response to the talc? 11 A Actually, no. That's the Heller article where 12 she sees it, but she specifically says she doesn't see 13 foreign-body giant cell reaction. 14 Q Can you reconcile that inconsistency if you 15 think that's how the body should respond to talc? 16 A Well, I think -- reconcile it is that I don't 17 think the talc is there having any biologic function or 18 is really in the tissue. It's a contaminant, and 19 that's why it didn't produce a biologic reaction. 20 Q Is it your opinion that all of the studies 21 that claim to recognize or identify talc in ovarian 22 tissue are what -- are really identifying 23 contamination? 24 A I think it's a significant issue. I can't 25 tell you all of them or not.</p>	<p style="text-align: right;">Page 276</p> <p>1 I want to ask you a question about it. I know that's 2 your position. 3 A Yeah. 4 Q Are you aware that there are many studies that 5 conclude that talc particles can, in fact, migrate from 6 the perineum to the ovaries? 7 MS. AHERN: Objection. Form. 8 THE WITNESS: From the perineum? 9 MR. DEARING: Yes. 10 THE WITNESS: No, I'm not aware of those. 11 BY MR. DEARING: 12 Q Are you aware that the 2007 study by 13 Dr. Cramer states that the presence of talc in lymph 14 nodes provides evidence that talc used externally is 15 capable of migrating into the pelvis? 16 MS. AHERN: Objection. Form. 17 THE WITNESS: Could -- do you have that paper, by 18 the way? 19 BY MR. DEARING: 20 Q I don't. 21 A I'd like to see the paper because I think 22 there are issues in there that are important to point 23 out. 24 Q Okay. The one paper I did bring that I 25 already showed you was McDonald's 2019 paper.</p>
<p style="text-align: right;">Page 275</p> <p>1 Q The fact is there's not a single study that 2 identifies talc particles in ovarian tissue that 3 recognizes a granulomatous giant cell response to it; 4 right? 5 MS. AHERN: Objection. Form. 6 THE WITNESS: As far as I know, that's correct. 7 BY MR. DEARING: 8 Q The next section of your report is entitled 9 "Migration of Talc to the Ovaries." 10 A Okay. 11 Q And I asked you earlier today if you thought 12 talc could migrate from the perineum to the ovaries and 13 you said absolutely not. 14 Is that still your position? 15 A Yes. I don't think it can migrate from the 16 perineum. 17 Q Specifically what you say is -- you say that 18 Dr. Kane's opinion that talcum powder applied to the 19 external perineum can migrate to the ovaries is 20 unsupported by and contrary to the current data and 21 understanding of ovarian cancer pathology. 22 A Where were you reading that? I'm sorry. I 23 know I said that, but can you see that -- show me that 24 exactly. 25 Q No, not without reading the whole thing. But</p>	<p style="text-align: right;">Page 277</p> <p>1 A Right. 2 Q Remember? 3 A This is a totally different one. 4 Q Right. She said that -- said that the talc 5 migrated to pelvic lymph nodes from perineal 6 application. 7 A Yeah. I don't see how she came to that 8 conclusion. 9 So, first of all, the 2007 study -- let me 10 make sure this is the correct. 2007. 11 Q The one I'm referring to is the pelvic lymph 12 node study. 13 A "Presence of talc in pelvic lymph nodes of a 14 woman with ovarian cancer and long-term genital 15 exposure to cosmetic talc." 16 Q Okay. 17 A Right. The first thing is that it's a case 18 report -- 19 Q Sure. 20 A -- which doesn't really tell you a lot in 21 terms of scientific evidence. This is just any case, 22 any case report. 23 Q A case where talc migrated to that lady's 24 ovaries from the perineum; right? 25 MS. AHERN: Objection. Form.</p>

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<p style="text-align: right;">Page 278</p> <p>1 THE WITNESS: Where does it say anything about it</p> <p>2 coming from the perineum? I didn't see that. It could</p> <p>3 have come from inhalation. I mean, I can tell you,</p> <p>4 coming from the peritoneum and going to a lymph node</p> <p>5 sounds totally against any method of lymphatic</p> <p>6 drainage.</p> <p>7 BY MR. DEARING:</p> <p>8 Q Do you believe --</p> <p>9 A Makes no sense.</p> <p>10 Q Do you believe that inhalation of talc can</p> <p>11 result in the deposition of talc particles on ovarian</p> <p>12 tissue?</p> <p>13 A It hasn't been demonstrated that I'm aware of.</p> <p>14 It has been talked about.</p> <p>15 Q You just said it could have come from</p> <p>16 inhalation.</p> <p>17 A Yeah. And I'm saying maybe that's how it came</p> <p>18 from, but there's no definite proof. But I don't think</p> <p>19 it --</p> <p>20 MS. AHERN: I think it is in your report. You</p> <p>21 cited it; right?</p> <p>22 THE WITNESS: Case report.</p> <p>23 BY MR. DEARING:</p> <p>24 Q Well, let me ask you about the two cases that</p> <p>25 you cite --</p>	<p style="text-align: right;">Page 280</p> <p>1 BY MR. DEARING:</p> <p>2 Q And this is a paper that you cite for support</p> <p>3 that talc cannot migrate from the perineum to the</p> <p>4 ovaries; right?</p> <p>5 A I'd have to see my report where we say that.</p> <p>6 I see that we -- we're referring to Venter and Egli and</p> <p>7 then we go to Wehner. Yes.</p> <p>8 Q At the top of page --</p> <p>9 A Wehner and Boorman. This is Wehner and</p> <p>10 Wehner.</p> <p>11 Q At the top of page 22, you say "notably</p> <p>12 Dr. Kane omits" and you mention the Wehner 1985 and</p> <p>13 Boorman 1995.</p> <p>14 A Right.</p> <p>15 Q "Wehner examined talc migration in</p> <p>16 monkeys, receiving repeated</p> <p>17 introductions of talc to the upper</p> <p>18 vagina over a period of 45 days.</p> <p>19 A Right.</p> <p>20 Q Right?</p> <p>21 A "No talc particles were found in the uterus or</p> <p>22 tubes."</p> <p>23 Q Right.</p> <p>24 A Yes. So they didn't find talc.</p> <p>25 Q So what's important I want to point out about</p>
<p style="text-align: right;">Page 279</p> <p>1 A Okay.</p> <p>2 Q -- to support your opinion.</p> <p>3 A Okay. Sure. I can't find it.</p> <p>4 Q One of them was the Wehner study. Do you</p> <p>5 remember the title is "On Talc Translocation from the</p> <p>6 Vagina to the Oviducts and Beyond," Alfred Wehner. I</p> <p>7 have a copy of it here if you would like.</p> <p>8 A Yeah. It would be nice to see the paper so I</p> <p>9 can --</p> <p>10 Q I thought you'd say that.</p> <p>11 (The document referenced below was</p> <p>12 marked Deposition Exhibit 12 for</p> <p>13 identification and is appended hereto.)</p> <p>14 BY MR. DEARING:</p> <p>15 Q This is Exhibit 12. This is a paper entitled</p> <p>16 "On Talc Translocation from the Vagina to the Oviducts</p> <p>17 and Beyond."</p> <p>18 A Okay.</p> <p>19 Q It is by Alfred Wehner and Dr. R.E. Weller;</p> <p>20 right?</p> <p>21 A Okay.</p> <p>22 MS. AHERN: I'm sorry. Do you have --</p> <p>23 MR. DEARING: Oh, you need a copy.</p> <p>24 MS. AHERN: Thank you.</p> <p>25 ///</p>	<p style="text-align: right;">Page 281</p> <p>1 the study is there were six monkeys studied over a</p> <p>2 45-day period with only 30 applications of talc; right?</p> <p>3 That's in the abstract. That's also in the body, but</p> <p>4 it is easier to find in the abstract.</p> <p>5 MS. AHERN: Objection. Form.</p> <p>6 THE WITNESS: Six monkeys received 30 applications.</p> <p>7 Yeah.</p> <p>8 BY MR. DEARING:</p> <p>9 Q And each of those six monkeys were at</p> <p>10 different menstrual cycle places; right?</p> <p>11 MS. AHERN: Objection. Form.</p> <p>12 THE WITNESS: Don't know that -- where it says</p> <p>13 that.</p> <p>14 BY MR. DEARING:</p> <p>15 Q The point is 30 applications over 45 days</p> <p>16 doesn't replicate long-term human genital talc use,</p> <p>17 does it?</p> <p>18 A No, not at all. So you're suggesting that</p> <p>19 negative finding supports what?</p> <p>20 Q No. I'm suggesting that your citing this</p> <p>21 study for the proposition that talc cannot migrate from</p> <p>22 the perineum to the ovaries in a human is misplaced --</p> <p>23 MS. AHERN: Objection. Form.</p> <p>24 BY MR. DEARING:</p> <p>25 Q -- because they're not the same thing.</p>

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<p style="text-align: right;">Page 282</p> <p>1 A But the point is to try to demonstrate, from 2 your standpoint, that it does get there. And there's 3 no study that shows that. I mean, you're supporting a 4 negative, which, to me, is nothing -- is not really 5 relevant. You want to support a positive. 6 Q You would agree with me that the cynomolgus 7 monkeys don't menstruate the way humans do; right? 8 A Oh, I don't know about that. 9 Q They do menstruate, but it's a different 10 process. 11 A I don't know why it's different. 12 MS. AHERN: Objection. Form. 13 THE WITNESS: I don't know. 14 BY MR. DEARING: 15 Q Do you know whether these cynomolgus monkeys 16 experience retrograde menstruation? 17 A No idea. 18 Q Right. Also, did you know that, at the time 19 of this study, Alfred Wehner was a paid consultant for 20 Johnson &amp; Johnson? 21 A No. 22 Q You also cite the Boorman study for the 23 proposition that talc cannot migrate from the perineum 24 to the ovaries in humans. 25 And, of course, this is a rat study; right?</p>	<p style="text-align: right;">Page 284</p> <p>1 genital talc use cannot -- that talc cannot migrate 2 from the perineum to the ovaries? 3 MS. AHERN: Objection. Form. 4 THE WITNESS: I think it's just supportive of the 5 studies that she quoted that says it does. 6 BY MR. DEARING: 7 Q Well, you criticized her study. 8 A Right. 9 Q So if it was just supportive, that means it's 10 not supportive at all; right? 11 MS. AHERN: Objection. Form. 12 THE WITNESS: So they're both not supportive. 13 BY MR. DEARING: 14 Q Okay. Fair enough. 15 In fact, the authors practically say that in 16 this study; right? 17 If you look at the last sentence of this 18 one-page report, it says, "In the extrapolation of 19 these data, one should consider limitations relative to 20 the marked anatomical and physiological differences 21 between rodents and humans; right?" 22 Do you see that last sentence? 23 A I'm sorry. I was looking at something else. 24 Q It's the last sentence of this paper. 25 A This Boorman paper?</p>
<p style="text-align: right;">Page 283</p> <p>1 MS. AHERN: Objection. Form. 2 BY MR. DEARING: 3 Q Rats and mice. Yes? 4 MS. AHERN: Same objection. 5 THE WITNESS: That's right. 6 (The document referenced below was 7 marked Deposition Exhibit 13 for 8 identification and is appended hereto.) 9 BY MR. DEARING: 10 Q In fact, it's a one-page rat study. Here it 11 is, if you'd like to refer to it. 12 Is this the study you were referencing to 13 support your proposition that talc can't migrate from 14 the perineum to the ovaries in humans? 15 MS. AHERN: Objection. Form. 16 THE WITNESS: Let me see. Boorman, Seely. Yes, 17 this looks like the study, 1995. Yes. 18 BY MR. DEARING: 19 Q Actually, you criticized Dr. Kane for not 20 mentioning the Boorman study; right? 21 You say, "Notably, Dr. Kane omits any mention 22 of Wehner of 1985 and Boorman 1991." 23 A Right. 24 Q And you think that this study, this Boorman 25 one-page rat study, supports the proposition that</p>	<p style="text-align: right;">Page 285</p> <p>1 Q Uh-huh. 2 A "In the extrapolation of these data, one 3 should consider limitations relative to the marked 4 anatomical and physiological differences between 5 rodents and humans." 6 Q Right. So the Boorman paper doesn't really 7 tell you much about whether talc can migrate to the 8 perineum -- from the perineum to the ovaries in humans; 9 right? 10 A That's correct. Interestingly, by the way, in 11 the earlier comment I made about the Cramer 2007 study, 12 I found the sentence -- I'd have to look it up in the 13 paper, but I say, "I note that Cramer 2007," which is 14 the study that we're talking about, "which Kane relies 15 on for a migration opinion, stated that 'there is no 16 proof that talc used externally reaches the pelvis.'" 17 Q Right. That's the -- that's the 2007 pelvic 18 lymph node study. 19 A Yes. 20 Q Right. 21 A The one we were talking about just a few 22 minutes ago. 23 Q Right. And the one I showed you earlier by 24 Dr. McDonald is a follow-up to that study, right, the 25 one that's Exhibit 6?</p>



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<p>1 A The one that was just published in -- when was 2 it? 3 Q This one was published this year. 4 A 2007, that was published. Okay. 5 Q This is the follow-up to that study; right? 6 MS. AHERN: Objection. Form. 7 BY MR. DEARING: 8 Q Well, if you would, go back to Exhibit 6. 9 A What's Exhibit 6? 10 Q It's the follow-up to the lymph node study. 11 It's entitled "Correlative Polarizing Light and 12 Scanning" -- 13 A Sandra McDonald. 14 Q Right. 15 A Since I haven't read that study, I'd like to 16 read it more carefully, because they don't describe how 17 they -- how they -- what tissues they examined, how 18 these patients were possibly exposed to talc. 19 Q They do explain all that. 20 A Where is it? 21 Q Well, I tell you what. Let's go off the 22 record, and you can take all the time you want to read 23 it and we can talk about it. 24 A Okay. 25 VIDEO OPERATOR BROWN: The time is now 5:02. Going</p>	<p>1 digestion of tissue taken from paraffin 2 blocks in scanning electron microscopy 3 with energy-dispersive x-ray analysis. 4 Talc particles correlated significantly 5 with surface contamination assessments 6 using polarized light microscopy. After 7 adjusting for surface contamination, 8 talc burdens in nodes correlated 9 strongly with perineal talc use. 10 "In a" -- let me just -- "In a 11 separate group of lymph nodes, 12 birefringent particles within the same 13 plane of focus as the tissues in the 14 histological sections were highly 15 correlated with talc particles within 16 the tissue by in situ, SEM-EDX. We 17 conclude that since talc can be a 18 surface contaminant from tissue 19 collection/preparation, digestion 20 measurements may be influenced by 21 contamination. Instead, because they 22 preserve anatomic landmarks and permit 23 identification of particles and cells in 24 tissues, polarized light microscopy and 25 in situ SEM-EDX are recommended to</p>
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<p>1 off the record. 2 (Recess taken.) 3 VIDEO OPERATOR BROWN: The time is now 5:22. Back 4 on the record. 5 BY MR. DEARING: 6 Q Doctor, have you now had an opportunity to 7 read this study entitled "Correlative Polarizing Light 8 and Scanning Electron Microscopy for the Assessment of 9 Talc in Pelvic Region Lymph Nodes"? 10 A I have. 11 Q In the abstract, it sets out sort of the 12 purpose and the methodology of this study. And it says 13 that: 14 "Perineal talc use is associated 15 with ovarian carcinoma in many 16 case-controlled studies. Such talc may 17 migrate to pelvic organs and regional 18 lymph nodes with both clinical and legal 19 significance. Our goal was to 20 differentiate talc in pelvic lymph nodes 21 due to exposure versus contamination 22 with talc in the laboratory. We studied 23 22 lymph nodes from ovarian tumor 24 patients, some of which had documented 25 talc exposure, to quantify talc using</p>	<p>1 assess talc in lymph nodes." 2 Do you agree that that's an accurate summary 3 of this study? 4 MS. AHERN: Objection. Form. 5 THE WITNESS: Pretty much. 6 BY MR. DEARING: 7 Q So one of the things we were talking about 8 before we went off the record so you could read this 9 study was that you said you weren't sure about the 10 exposure of the patients in this study. 11 And if you would turn to page 2 at the top, it 12 says: 13 "One exposure of great current 14 medical, public health, and medicolegal 15 importance is the association of ovarian 16 cancers with the use of talc cosmetic 17 products in the genital area. Data 18 related to this association come from 19 epidemiologic studies which identified a 20 clear excess of women with ovarian 21 malignancy who had used talc in their 22 genital area prior to developing cancer 23 compared to control women." 24 Do you agree with that last sentence of these 25 six scientists that data related to this association</p>

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<p style="text-align: right;">Page 290</p> <p>1 come from epidemiologic studies which identified a</p> <p>2 clear excess of women with ovarian malignancy who had</p> <p>3 used talc in their genital area prior to developing</p> <p>4 cancer compared to the control women?</p> <p>5 A I'm not sure what they mean by "clear."</p> <p>6 Q So you don't know how to interpret that</p> <p>7 sentence at all?</p> <p>8 MS. AHERN: Objection. Form.</p> <p>9 THE WITNESS: I mean, there have been epidemiologic</p> <p>10 studies that have demonstrated an association between</p> <p>11 talc usage and ovarian cancer. I don't argue that.</p> <p>12 BY MR. DEARING:</p> <p>13 Q And then he goes on to cite an epidemiological</p> <p>14 study two sentences farther down.</p> <p>15 "The most recent summary of the epidemiologic</p> <p>16 data in 2018" -- I guess at the time he was working --</p> <p>17 they were working on this paper -- "found that genital</p> <p>18 talc may increase the risk of ovarian carcinoma by</p> <p>19 about 30 percent."</p> <p>20 And then he's, of course, referring to the</p> <p>21 Penninkilampi study.</p> <p>22 A That's a relative risk, about 1.3 or</p> <p>23 something.</p> <p>24 Q Do you agree that the Penninkilampi shows a</p> <p>25 relative risk of 30 percent?</p>	<p style="text-align: right;">Page 292</p> <p>1 "A subset of authors from the</p> <p>2 present study have previously described</p> <p>3 a case report in which a woman with</p> <p>4 serous carcinoma of the ovary had a</p> <p>5 history of talc usage in her genital</p> <p>6 area, was demonstrated to have talc in</p> <p>7 three of four pelvic -- examined pelvic</p> <p>8 lymph nodes."</p> <p>9 So when we were talking about the exposure</p> <p>10 history in the 2007 Cramer case and you said "I don't</p> <p>11 know if she used perineal talc," you now do know that</p> <p>12 that was a perineal talc exposure; right?</p> <p>13 MS. AHERN: Objection. Form.</p> <p>14 THE WITNESS: Well, she claims to have perineal</p> <p>15 talc exposure, and then these exposure -- and you find</p> <p>16 talc in the lymph nodes, but that does not directly</p> <p>17 prove that it got there through the female reproductive</p> <p>18 tract.</p> <p>19 BY MR. DEARING:</p> <p>20 Q But the only evidence of exposure in the 2007</p> <p>21 Cramer study is the statement by the patient that she</p> <p>22 used talc perineally; right?</p> <p>23 MS. AHERN: Objection to form.</p> <p>24 BY MR. DEARING:</p> <p>25 Q You're speculating about any other talc</p>
<p style="text-align: right;">Page 291</p> <p>1 MS. AHERN: Objection to form.</p> <p>2 THE WITNESS: Well, by 1.3, right. I just looked</p> <p>3 at the abstract on that study, by the way.</p> <p>4 BY MR. DEARING:</p> <p>5 Q Okay. He goes down to describe the Heller</p> <p>6 study in that same column. And that's a study that we</p> <p>7 briefly touched on earlier.</p> <p>8 A Uh-huh.</p> <p>9 Q But he says:</p> <p>10 "A study by Heller was done with</p> <p>11 digestion techniques followed by TEM" --</p> <p>12 that's transmission electron</p> <p>13 microscopy -- "on ovaries from 24 women</p> <p>14 having hysterectomy, oophorectomy, for</p> <p>15 reasons other than ovarian malignancy.</p> <p>16 The study found talc in approximately</p> <p>17 half the samples, with no obvious</p> <p>18 correlation with the genital talc use</p> <p>19 history, thereby suggesting to the</p> <p>20 authors that talc exposure may be</p> <p>21 relatively ubiquitous across the</p> <p>22 population."</p> <p>23 And then he talks about Dr. Cramer's and</p> <p>24 Godleski's 2007 case report that we were talking about</p> <p>25 prior to the break. He said:</p>	<p style="text-align: right;">Page 293</p> <p>1 exposure; right?</p> <p>2 MS. AHERN: Objection. Form.</p> <p>3 THE WITNESS: Well, I can't -- yeah. I mean, it</p> <p>4 doesn't prove necessarily that -- passage through the</p> <p>5 female reproductive tract. It could have been inhaled.</p> <p>6 BY MR. DEARING:</p> <p>7 Q Next, it says in the next paragraph:</p> <p>8 "In the study reported here, we</p> <p>9 assess talc in a sizeable set of lymph</p> <p>10 nodes in the pelvic region representing</p> <p>11 multiple patients; thus, we expanded on</p> <p>12 the lymph node analysis in the previous</p> <p>13 case report" -- talking about the Cramer</p> <p>14 2007 report -- "as well as the study of</p> <p>15 nonmalignant ovaries by Heller, et al.,</p> <p>16 and we examined nodes in 22 patients</p> <p>17 with various types of ovarian tumors."</p> <p>18 So do you agree that this study is in part</p> <p>19 a -- an expansion of Dr. Cramer's 2007 -- Dr. Cramer's</p> <p>20 2007 case report and Dr. Heller's study?</p> <p>21 A It's a follow-up, yeah. Okay.</p> <p>22 Q Okay. And part of the study here is that they</p> <p>23 assessed -- in the next column at the top, they assess</p> <p>24 tissue surface contamination as a factor explaining the</p> <p>25 high talc burden in some cases as opposed to talc that</p>

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<p style="text-align: right;">Page 294</p> <p>1 migrated to the nodes from perineal exposure.  2 So, clearly, they are surmising or suggesting  3 that the talc found in the lymph nodes in this study  4 migrated to those lymph nodes from perineal exposure;  5 right?  6 MS. AHERN: Objection. Form.  7 THE WITNESS: Well, as I said, you can't -- you  8 can't -- that's a big jump. They don't show you -- I  9 mean, they're just saying she had perineal exposure.  10 Okay. And she has talc in these lymph nodes.  11 It doesn't mean that it went through the  12 vagina, the cervix, the uterus, the ovaries, and  13 somehow got into the lymph nodes.  14 BY MR. DEARING:  15 Q Well, these eight authors concluded that that  16 exposure, the perineal exposure, is what resulted in  17 the presence of talc in the lymph nodes; right?  18 MS. AHERN: Objection. Form.  19 THE WITNESS: They concluded that, but I don't see  20 why -- they didn't give the alternate explanation, that  21 it possibly got through inhalation. It makes more  22 sense to me than coming through the vagina or the  23 vulva -- from the vulva.  24 BY MR. DEARING:  25 Q Inhalation of talc particles depositing on</p>	<p style="text-align: right;">Page 296</p> <p>1 plausible.  2 BY MR. DEARING:  3 Q So something can be more likely, in your  4 mind --  5 A Yeah.  6 Q -- without being biologically plausible?  7 A Right.  8 Q And, of course, one of the advantages of using  9 SEM-EDX, according to these eight scientists, is that  10 it allows you to observe the talc particle in situ --  11 in other words, in the tissue -- not on the surface of  12 the tissue; right?  13 MS. AHERN: Objection. Form.  14 THE WITNESS: Well, I'm not an electron  15 microscopist, so I can't really comment on their  16 technology of avoiding contamination, which they,  17 frankly, acknowledge could be a significant problem.  18 So I'd have to depend on someone who is an  19 electron microscopist to really go over their  20 methodology and say, oh, yes, this really is purified.  21 I mean, cutting the section off the surface, I don't  22 think that necessarily excludes contamination.  23 But, again, I'm not an electron microscopist.  24 I think that needs to be evaluated by someone who is.  25 ///</p>
<p style="text-align: right;">Page 295</p> <p>1 ovarian tissue or pelvic lymph nodes is more plausible  2 to you than perineal application?  3 A Yes.  4 Q Are you saying that inhalation of talc  5 particles depositing on ovarian -- on ovaries or in  6 pelvic lymph nodes is a biologically plausible  7 mechanism of exposure?  8 MS. AHERN: Objection. Form.  9 THE WITNESS: Repeat that, please.  10 MR. DEARING: Sure.  11 BY MR. DEARING:  12 Q I believe you just said it was more likely, in  13 your opinion, that the talc particles observed in the  14 pelvic lymph nodes in this study got there through  15 inhalation and -- as opposed to perineal exposure and  16 migration.  17 My question is, by saying that, are you saying  18 that it's biologically plausible that you can -- that a  19 person can inhale talc and have those particles  20 deposited on ovarian tissue or pelvic lymph nodes?  21 MS. AHERN: Objection. Form.  22 THE WITNESS: I didn't say anything about  23 biologically plausible; I'm saying that I think it's  24 more likely -- it's hypothesis. And that needs to be  25 proven before it's accepted as being biologically</p>	<p style="text-align: right;">Page 297</p> <p>1 BY MR. DEARING:  2 Q Right. Well, at least three of these authors  3 are electron microscopists. So would you defer to them  4 when they say that SEM-EDX methodologies is the best  5 way to evaluate talc particles in situ or in tissue?  6 A No.  7 MS. AHERN: Objection. Form.  8 THE WITNESS: I would not defer to them. I would  9 think you need an independent -- I mean, it's the same  10 idea. It would have to be -- now, I realize the study  11 got published, but I still would like to have someone  12 else who's an electron microscopist to tell me to  13 review that paper and say, yes, that makes sense. I  14 can't do that.  15 BY MR. DEARING:  16 Q If there are three of the eight authors of  17 this study who are electron microscopists saying that,  18 why do you need more?  19 MS. AHERN: Objection.  20 THE WITNESS: It does -- I mean, they're -- I'm not  21 saying necessarily biased, but they want to prove a  22 case. So they're going to say, oh, yeah, this shows  23 it.  24 I'd like an independent review by someone who  25 is an electron microscopist who says yes, that's a</p>

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<p style="text-align: right;">Page 298</p> <p>1 reasonable way of doing it and avoids contamination.  2 As I said, I'm not in a position to do that.  3 BY MR. DEARING:  4 Q Do you agree that the women studied in this  5 publication who are in this study all claimed that they  6 used talc for feminine hygiene?  7 A No, I don't think they all did. I think there  8 were some that said they were exposed, but I think  9 others said they weren't.  10 Q On page 3 at the top, the beginning of the  11 first paragraph, it says "Talc is readily visible under  12 polarizing light microscopy."  13 A Yes.  14 Q You agree with that; right?  15 A Well, that's what they say, yeah.  16 Q Well, you've --  17 A Oh, yeah, generally speaking, yes. Yes.  18 Q I mean, you understand how polarizing light  19 microscopes work and how they will illuminate particles  20 with birefringent properties?  21 A I use it.  22 Q And it also says that talc may be found as  23 both plates and fibrous forms. And I believe you don't  24 have an opinion about the fibrous forms; right?  25 A Right.</p>	<p style="text-align: right;">Page 300</p> <p>1 are closed under normal conditions -- get through the  2 vagina, get through the cervix -- which, most of the  3 time, is closed to passage of bacteria, sperm, except  4 at the time of the -- when women ovulate -- get through  5 the uterus, get through the fallopian tubes, and get  6 into the peritoneal cavity. I don't think that's  7 possible. Unlike the lungs and the mouth, there's an  8 open airway. That, to me, is more likely than going  9 through that complicated route through the genital  10 tract.  11 Q Do you also recall reading in this study that  12 these eight authors suggested, and might have proved,  13 that one of the flaws in the Heller study was that the  14 technique used for determining the fiber burden in the  15 ovarian tissue of the women was transmission, EM, in  16 which they digested the tissue and thereby brought in  17 the surface contaminants that Dr. Godleski and McDonald  18 and Cramer and Welch and everyone else says that you  19 have to be careful to avoid?  20 MS. AHERN: Is there a question? I'm sorry.  21 MR. DEARING: Yeah.  22 THE WITNESS: Yeah.  23 MS. AHERN: Objection. Sorry.  24 THE WITNESS: No, no. I think I'm getting --  25 please repeat the question.</p>
<p style="text-align: right;">Page 299</p> <p>1 Q And where the particles of fibers are brightly  2 birefringent and often in the size range of 1 to 10  3 microns. We've already discussed that?  4 A Right.  5 Q And then do you see at the bottom of page 3,  6 right-hand side, next-to-the-last sentence, it states  7 what the eight authors' position was with regard to  8 exposure.  9 It says "The birefringent particles present  10 within lymph nodes were taken to indicate clinically  11 significant talc that migrated there through the  12 lymphatic system"; right?  13 A That's what they say.  14 MS. AHERN: Objection to form.  15 THE WITNESS: Yes.  16 BY MR. DEARING:  17 Q So we talked about migration through the  18 genital tract. Do you have an opinion about whether  19 perineal talc use can result in talc migration through  20 the lymphatics to lymph nodes?  21 A Well, in order to get to the lymphatics, they  22 have to get into the peritoneal cavity. So, as I said  23 before, I don't believe -- and this, to me -- and this  24 study doesn't prove it either, that talc particles on  25 the perineum can get through the labia majora -- which</p>	<p style="text-align: right;">Page 301</p> <p>1 MR. DEARING: Sure.  2 BY MR. DEARING:  3 Q So one of the things this study addresses is  4 the Heller study. And it's a continuation of the  5 Heller study. And they're offering an explanation for  6 why the burden count for talc particles in the Heller  7 study seems to be inconsistent across the board with  8 women who acknowledge being exposed to talc and women  9 who either didn't know or -- or denied using talc.  10 A Correct.  11 Q Okay. And what they say in this study is that  12 the problem with the Heller study was they digested the  13 tissue and then counted the fibers. And by digesting  14 the tissue -- or particles, talc particles, by  15 digesting the tissue, you necessarily bring in surface  16 contaminants so that the particles that you're  17 calculating or quantifying are just as likely to be  18 surface contaminants as anything else; right?  19 MS. AHERN: Objection. Form.  20 THE WITNESS: That's what they claim.  21 BY MR. DEARING:  22 Q Do you have any disagreement with them, with  23 that analysis of the Heller methodology?  24 A I think --  25 MS. AHERN: Objection to form.</p>

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<p style="text-align: right;">Page 302</p> <p>1 THE WITNESS: I think that that's -- could be 2 contamination, yes. That's what I said earlier. 3 BY MR. DEARING: 4 Q On page 11, they start summarizing their 5 findings on the right-hand column -- 6 A Hold it. Hold it. 7 Q I'm sorry. Page 13. 8 A Okay. 9 Q Right-hand column, three-quarters of the way 10 down, it says: 11 "In the long-studied and debated 12 association between talc exposure and 13 ovarian cancer, our study provides 14 additional evidence that talc may enter 15 pelvic tissues and ultimately be 16 detected and measured in regional lymph 17 nodes, and this relationship became 18 especially strong when clinical-use data 19 was considered and surface contamination 20 was corrected for statistically. This 21 adds perspective to the known migratory 22 capabilities and overall biological 23 role/impact of talc." 24 Do you agree with the statement that the 25 findings of this study provide additional evidence that</p>	<p style="text-align: right;">Page 304</p> <p>1 clinicians should consider broader inquiries with their 2 patients about talc usage when they're suffering from 3 ovarian cancer? 4 MS. AHERN: Objection. Form. 5 THE WITNESS: I'm not here to make recommendations 6 for how patients should be advised. 7 BY MR. DEARING: 8 Q Well, do you agree that, since there are 9 suggestions that pelvic lymph nodes may -- may gather 10 or store foreign particles that may have contributed to 11 cancer, to ovarian cancers, do you agree with the 12 statement here that pathologists may wish to consider 13 greater -- may wish to pay greater attention to sampled 14 regional lymph nodes? 15 MS. AHERN: Objection. Form. 16 THE WITNESS: There's no data in this study to say, 17 even if they were correct in saying that talc is in 18 lymph nodes, that it has any bearing on the development 19 of ovarian cancer. Nothing whatsoever. I've never 20 heard of development of ovarian cancer based on 21 material that's in lymph nodes. 22 BY MR. DEARING: 23 Q If that's true -- 24 A It's biologically not plausible to me. 25 Q If that's true, why do at least three of your</p>
<p style="text-align: right;">Page 303</p> <p>1 talc may enter the pelvic tissues and ultimately be 2 detected and measured in lymph nodes? 3 MS. AHERN: Objection. Form. 4 THE WITNESS: As I said a few minutes ago, I do not 5 have the technical expertise in electron microscopy to 6 critically evaluate the techniques that they claim 7 avoided the contamination issue. So I cannot, at this 8 point, agree with that. 9 BY MR. DEARING: 10 Q Dr. Cramer, who participated in this study, is 11 an OB/GYN; right? 12 A Yes. 13 Q So with regard to a practical application of 14 this study for an OB/GYN, the authors write: 15 "Our findings also suggest that in 16 patients with ovarian cancer, clinicians 17 may want to make broader inquiries into 18 the past and present use of talc by 19 their patients. Similarly, pathologists 20 may wish to pay greater attention to 21 sampled regional lymph nodes." 22 First of all, do you agree that, in light of 23 the studies, whether you agree with them or not, and in 24 light of the -- in light of the universe of studies 25 looking at talc and ovarian cancer, do you agree that</p>	<p style="text-align: right;">Page 305</p> <p>1 textbooks identify talc as a risk factor for ovarian 2 cancer? 3 MS. AHERN: Objection. Form. 4 THE WITNESS: Well, a risk factor has nothing to do 5 with its presence in lymph nodes. 6 BY MR. DEARING: 7 Q Well, risk factors have to do with a woman's 8 increased risk of getting ovarian cancer; right? 9 MS. AHERN: Objection. Form. 10 THE WITNESS: It doesn't tell you anything about 11 the mechanism, though. 12 MR. DEARING: I'm going to move to strike your last 13 answer as nonresponsive. 14 BY MR. DEARING: 15 Q My question was, well, risk factors have to do 16 with a woman's increased risk of getting ovarian 17 cancer; right? That's the question. 18 MS. AHERN: Objection. Form. 19 THE WITNESS: I said, yes, increased risk. A truly 20 accepted risk factor means that there's a risk of 21 developing ovarian cancer. We discussed that issue of 22 risk factors earlier and that there are weaker risk 23 factors and stronger risk factors, and I would still 24 adhere to that statement. 25 ///</p>



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<p style="text-align: right;">Page 306</p> <p>1 BY MR. DEARING:</p> <p>2 Q Do you know whether your new Blaustein's</p> <p>3 edition is going to identify talc as a risk factor for</p> <p>4 ovarian cancer, talc use?</p> <p>5 A It will be mentioned, but not in the kind of</p> <p>6 detail that you asked me earlier. Again, to represent</p> <p>7 the broad, general notion of what's out there.</p> <p>8 Q In the next-to-the-last paragraph in the last</p> <p>9 sentence, it says, "Our findings yield important</p> <p>10 insights as to the ability of talc to migrate to</p> <p>11 nodes."</p> <p>12 A Wait, wait, wait. I'm not seeing it.</p> <p>13 Q I'm sorry. Page 14.</p> <p>14 A Yeah. Okay. 14.</p> <p>15 Q Last sentence, next-to-last --</p> <p>16 A "Our findings yield important" -- okay.</p> <p>17 Q "Our findings yield important</p> <p>18 insights as to the ability of talc to</p> <p>19 migrate to nodes and under what</p> <p>20 conditions its identification to nodes</p> <p>21 and tissues is clinically meaningful and</p> <p>22 when not."</p> <p>23 So do you disagree that this paper offers</p> <p>24 important insights as to the ability of talc to migrate</p> <p>25 to nodes?</p>	<p style="text-align: right;">Page 308</p> <p>1 that should have been used as -- to buttress our</p> <p>2 arguments.</p> <p>3 BY MR. DEARING:</p> <p>4 Q Do you have any other criticisms of her</p> <p>5 methodology as far as how she reached the opinions she</p> <p>6 reached?</p> <p>7 A Well, as I said, there's some specific issues</p> <p>8 that I've listed in the paper. We've addressed some of</p> <p>9 them, like analogy. There's others that I mentioned as</p> <p>10 well. But, again, since it fails right from the</p> <p>11 beginning not identifying the appropriate tissue to</p> <p>12 study in terms of a precursor, everything else after it</p> <p>13 goes by the wayside.</p> <p>14 Q As far as you know, have you identified all of</p> <p>15 methodological disagreements with her in your report?</p> <p>16 MS. AHERN: Objection. Form. Asked and answered.</p> <p>17 THE WITNESS: Well, in my report and what I've</p> <p>18 stated here in the deposition.</p> <p>19 BY MR. DEARING:</p> <p>20 Q Speaking of relying on the wrong studies, back</p> <p>21 to the migration -- I forgot to ask you a question.</p> <p>22 So you relied on the monkey study and the</p> <p>23 mouse study, and I think you can see it may have little</p> <p>24 or no relevance to the human transmigration. But if</p> <p>25 you're going to consider animal studies to either</p>
<p style="text-align: right;">Page 307</p> <p>1 MS. AHERN: Objection. Form.</p> <p>2 THE WITNESS: Well, as I said earlier, I still am</p> <p>3 not -- since I'm unable to truly evaluate their</p> <p>4 procedure to prevent migration and to really pin down</p> <p>5 if talc is in ovarian tissues, I can't comment on the</p> <p>6 validity and my impression of this analysis.</p> <p>7 BY MR. DEARING:</p> <p>8 Q So we spent a good bit of time talking about</p> <p>9 your criticisms of Dr. Kane. Let me just ask you, do</p> <p>10 you have any criticism of her opinions that are not</p> <p>11 contained in your report?</p> <p>12 A I think it's all there.</p> <p>13 Q And with regard to her methodology for</p> <p>14 evaluating the issues of talc and ovarian cancer, you</p> <p>15 testified you have a problem with her methodology in</p> <p>16 that she relied on studies that you think should not</p> <p>17 have been relied on. Is that a fair statement?</p> <p>18 MS. AHERN: Objection. Form.</p> <p>19 THE WITNESS: Yes. Specifically, I said she relied</p> <p>20 on studies utilizing ovarian epithelial cells, surface</p> <p>21 ovarian epithelial cells, to bolster her argument that</p> <p>22 the studies that she cited were indicative of causation</p> <p>23 of ovarian cancer when I said that the private -- that</p> <p>24 the -- that the precursor lesions really were in the</p> <p>25 fallopian tube and that should have been the tissue</p>	<p style="text-align: right;">Page 309</p> <p>1 support or refute the idea of talc migrating from the</p> <p>2 perineum to the ovaries or from the vagina to the</p> <p>3 ovaries, you didn't mention the Phillips study.</p> <p>4 Are you familiar with the Phillips study?</p> <p>5 It's a rabbit study.</p> <p>6 MS. AHERN: Objection. Form. Mischaracterizing</p> <p>7 testimony.</p> <p>8 THE WITNESS: I would have to see it.</p> <p>9 BY MR. DEARING:</p> <p>10 Q You don't remember it?</p> <p>11 A No.</p> <p>12 Q It was a study where they injected talc into</p> <p>13 the vagina of a rat and discovered that it did</p> <p>14 migrate -- I mean of a rabbit, and discovered that it</p> <p>15 did migrate to the tubes.</p> <p>16 Does that not sound familiar to you at all?</p> <p>17 MS. AHERN: Objection. Form.</p> <p>18 THE WITNESS: If you had the paper, it may jog my</p> <p>19 memory and I can comment.</p> <p>20 BY MR. DEARING:</p> <p>21 Q I don't have it. I'm just asking if you --</p> <p>22 A Okay. Off the top of my head, I don't</p> <p>23 remember that particular study. I did evaluate a</p> <p>24 number of them.</p> <p>25 But, again, just as you said, they introduced</p>

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<p style="text-align: right;">Page 310</p> <p>1 the talc -- was it talc that they used?</p> <p>2 Q Yes.</p> <p>3 A They introduced it into the vagina. So that</p> <p>4 immediately short-circuits one of the major barriers,</p> <p>5 which is from the perineum to get to the vagina. I</p> <p>6 mean, it's closed. The vulva is closed. The labia</p> <p>7 touch each other. Without physically opening them,</p> <p>8 something can't get into it.</p> <p>9 Q Well, if talc could get inside the vagina,</p> <p>10 does that change your opinion at all about whether it</p> <p>11 can migrate further?</p> <p>12 MS. AHERN: Objection. Form.</p> <p>13 THE WITNESS: First of all, I would just repeat --</p> <p>14 or say if it got into the vagina, and I'd say it can't</p> <p>15 get into the vagina.</p> <p>16 BY MR. DEARING:</p> <p>17 Q I know.</p> <p>18 A And then there was a study that I cited in</p> <p>19 which they did -- let me see if I can find it. They</p> <p>20 put particles, not talc, into the -- where is</p> <p>21 migration? -- into the -- into the vagina. Let's see.</p> <p>22 I should be able to find that. Migration.</p> <p>23 Okay. Here. On page 22, in the second</p> <p>24 paragraph. You highlighted it:</p> <p>25 "It should be noted that even when</p>	<p style="text-align: right;">Page 312</p> <p>1 hygiene where she just pours talc in her panties, which</p> <p>2 a lot of these plaintiffs have done, and then she has</p> <p>3 intercourse that day, wouldn't that force some of the</p> <p>4 talc particles presumably into the vagina?</p> <p>5 MS. AHERN: Objection. Form.</p> <p>6 THE WITNESS: If it's still there, present at the</p> <p>7 time of having intercourse, I don't know.</p> <p>8 BY MR. DEARING:</p> <p>9 Q Well --</p> <p>10 A It depends how much is there. I mean, it's</p> <p>11 totally speculation. I can't comment on that.</p> <p>12 Q Is it biologically plausible that talc can be</p> <p>13 forced into the vagina if used externally --</p> <p>14 A No, I don't think that's --</p> <p>15 Q -- during intercourse?</p> <p>16 A -- biologically plausible.</p> <p>17 Q You don't?</p> <p>18 A No.</p> <p>19 Q This study that you're referring to actually</p> <p>20 supports what I was suggesting early on that you</p> <p>21 disagreed with me on, and that was that, if talc was</p> <p>22 introduced into the uterus, you said you still didn't</p> <p>23 think it would migrate to the tubes or to the ovaries.</p> <p>24 But this dye did exactly that, didn't it? It</p> <p>25 was introduced into the uterus, and in 50 percent of</p>
<p style="text-align: right;">Page 311</p> <p>1 particles are placed into the vagina,</p> <p>2 passage to the ovaries is quite unusual.</p> <p>3 For example, in another study it was</p> <p>4 reported that when India ink was</p> <p>5 introduction into the uterus, it was</p> <p>6 detected in the fallopian tubes in 50</p> <p>7 percent of women and, when introduced</p> <p>8 into the cervix, it was detected in the</p> <p>9 fallopian tubes of just 30 percent of</p> <p>10 women. When it was introduced into the</p> <p>11 vagina, it was detected in only 1 of 37,</p> <p>12 0.02 percent, patients. In short, the</p> <p>13 vulva is not an open conduit to the</p> <p>14 vagina and, therefore, none of these</p> <p>15 highly artificial studies can be used to</p> <p>16 assert that talc applied to the external</p> <p>17 perineum migrates to the fallopian tubes</p> <p>18 and ovaries."</p> <p>19 BY MR. DEARING:</p> <p>20 Q So your opinion is talc cannot get into the</p> <p>21 vagina under any circumstance; right?</p> <p>22 MS. AHERN: Object to the form.</p> <p>23 THE WITNESS: I said that, yes.</p> <p>24 BY MR. DEARING:</p> <p>25 Q So if a woman uses talc daily for feminine</p>	<p style="text-align: right;">Page 313</p> <p>1 the women it migrated to the fallopian tubes; right?</p> <p>2 MS. AHERN: Objection. Form.</p> <p>3 THE WITNESS: Of course, these are part India ink,</p> <p>4 not talc. So it's not a great substitute.</p> <p>5 BY MR. DEARING:</p> <p>6 Q Well, there are some materials, if introduced</p> <p>7 into the uterus, that would migrate at least half the</p> <p>8 time, according to this study, into the fallopian</p> <p>9 tubes; right?</p> <p>10 MS. AHERN: Objection. Form.</p> <p>11 THE WITNESS: India ink.</p> <p>12 BY MR. DEARING:</p> <p>13 Q Same question with the cervix. So there are</p> <p>14 some materials that, if introduced in the cervix, could</p> <p>15 migrate to the fallopian tube perhaps a third of the</p> <p>16 time?</p> <p>17 MS. AHERN: Objection. Form.</p> <p>18 THE WITNESS: Let's get down to the real -- real</p> <p>19 reality. When you get to the vagina, which is what</p> <p>20 you're talking about, introducing it in the vagina all</p> <p>21 the time, it occurred in 0.02 percent. Furthermore,</p> <p>22 that in and of itself is artificial, as I said. We're</p> <p>23 talking about perineal application, not introduction</p> <p>24 into the vagina, into the cervix, or into the uterus.</p> <p>25 ///</p>

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<p style="text-align: right;">Page 314</p> <p>1 BY MR. DEARING:</p> <p>2 Q On your supplemental reference list -- I know</p> <p>3 you didn't prepare this list, but there's a study on</p> <p>4 this list entitled Sjosten. It's spelled</p> <p>5 S-j-o-s-t-e-n. And it's entitled "Retrograde Migration</p> <p>6 of Glove Powder in the Human Female Genital Tract."</p> <p>7 In that study -- that study actually finds or</p> <p>8 found that talc deposited in the vagina from glove</p> <p>9 powder -- it was a starch powder -- migrated up the</p> <p>10 female genital tract.</p> <p>11 Do you recall that study? Do you know that</p> <p>12 study?</p> <p>13 MS. AHERN: Objection. Form.</p> <p>14 THE WITNESS: Well, it's listed, but I haven't read</p> <p>15 that study. But, again, glove powder means it was</p> <p>16 placed into the vagina on pelvic examination.</p> <p>17 BY MR. DEARING:</p> <p>18 Q Right.</p> <p>19 A Not on the vulva. Oh, and by the way --</p> <p>20 Q It doesn't stay there. It didn't stay there</p> <p>21 in this study. It migrated.</p> <p>22 MS. AHERN: Objection. Form.</p> <p>23 THE WITNESS: From the?</p> <p>24 BY MR. DEARING:</p> <p>25 Q From the vagina.</p>	<p style="text-align: right;">Page 316</p> <p>1 MS. AHERN: Objection. Form.</p> <p>2 THE WITNESS: I thought I went over that</p> <p>3 methodology right in the beginning.</p> <p>4 BY MR. DEARING:</p> <p>5 Q Well, you talked about a general methodology</p> <p>6 based on your experience, your research; but you</p> <p>7 haven't explained how you actually weigh the evidence</p> <p>8 of the things that you consider.</p> <p>9 MS. AHERN: Objection. Form.</p> <p>10 THE WITNESS: Well, I read over Dr. Kane's report.</p> <p>11 I ran down her references. And, as I said earlier, the</p> <p>12 papers that she relied on did not assess or did not</p> <p>13 buttress her arguments about the causation of ovarian</p> <p>14 cancer based on talc usage because they didn't examine</p> <p>15 the right tissues. And I've said that before, and I</p> <p>16 still say that.</p> <p>17 Then all the rest of it, like a set of</p> <p>18 dominoes, falls because, in order to establish</p> <p>19 causation, you need to look not at cancers, which many</p> <p>20 of the studies that she cited looked at because of</p> <p>21 increased inflammation, it's irrelevant. What you have</p> <p>22 to look at is the cell of origin of ovarian cancer,</p> <p>23 which we now acknowledge comes from tubal epithelium,</p> <p>24 and the studies that she looked at didn't analyze tubal</p> <p>25 epithelium.</p>
<p style="text-align: right;">Page 315</p> <p>1 A We talked about that already, the vagina</p> <p>2 studies described earlier.</p> <p>3 But I should also -- because you asked about</p> <p>4 sexual intercourse. And I could also -- I remember</p> <p>5 that -- it was an epidemiologic study. I can't, off</p> <p>6 the top of my head, remember which one, but I know that</p> <p>7 they evaluated talc in diaphragms, and that was not</p> <p>8 associated with an increased risk of ovarian cancer</p> <p>9 either.</p> <p>10 MR. DEARING: Can we take just a quick break? I</p> <p>11 think I'm almost finished.</p> <p>12 VIDEO OPERATOR BROWN: Time is now 5:59. Going off</p> <p>13 the record.</p> <p>14 (Recess taken.)</p> <p>15 VIDEO OPERATOR BROWN: Time is now 6:10. Back on</p> <p>16 the record.</p> <p>17 BY MR. DEARING:</p> <p>18 Q Doctor, in reviewing your report, I notice</p> <p>19 that your methodology for weighing the evidence on</p> <p>20 these issues that we've been discussing is not</p> <p>21 described.</p> <p>22 Can you describe for me what your methodology</p> <p>23 is with regarding to weighing the evidence as it</p> <p>24 pertains to the causation, migration, inflammation, the</p> <p>25 issues we've been discussing?</p>	<p style="text-align: right;">Page 317</p> <p>1 BY MR. DEARING:</p> <p>2 Q Do you agree that, when a physician or</p> <p>3 scientist is assessing or forming opinions on issues</p> <p>4 like causation, inflammation, migration, that it's</p> <p>5 important for that physician or scientist to consider</p> <p>6 all of the relevant literature on those topics?</p> <p>7 MS. AHERN: Objection. Form.</p> <p>8 THE WITNESS: Well, I don't know if you can ever</p> <p>9 say all of it. You try your best to read as much as</p> <p>10 you possibly can of the relevant literature and come to</p> <p>11 a conclusion.</p> <p>12 BY MR. DEARING:</p> <p>13 Q You agree with me that you've not done a</p> <p>14 comprehensive review of the literature on talc and</p> <p>15 inflammation?</p> <p>16 A I'm sorry. Could you repeat that?</p> <p>17 MS. AHERN: Objection. Form.</p> <p>18 BY MR. DEARING:</p> <p>19 Q I said do you agree with me that you have not</p> <p>20 done a comprehensive review of all of the relevant</p> <p>21 literature on the issue of talc and inflammation?</p> <p>22 MS. AHERN: Objection. Form.</p> <p>23 THE WITNESS: Well, as I said, I've reviewed many,</p> <p>24 many studies, and you can form an evaluation as these</p> <p>25 studies play out one way or the other. But all, every</p>

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<p style="text-align: right;">Page 318</p> <p>1 conceivable study? No, I didn't do that.</p> <p>2 BY MR. DEARING:</p> <p>3 Q Well, the studies that you considered are</p> <p>4 listed in your reference materials; right? Your two</p> <p>5 reference lists; right?</p> <p>6 A Yes.</p> <p>7 MS. AHERN: Objection. Form.</p> <p>8 BY MR. DEARING:</p> <p>9 Q In fact, some of the studies on the second</p> <p>10 reference list you didn't consider because you didn't</p> <p>11 even read; right?</p> <p>12 A Right.</p> <p>13 Q So if the studies aren't on your reference</p> <p>14 list, you did not consider them in forming your</p> <p>15 opinions that we've been discussing today; right?</p> <p>16 MS. AHERN: Objection. Form.</p> <p>17 THE WITNESS: That is correct.</p> <p>18 BY MR. DEARING:</p> <p>19 Q So is it fair to say that you did not do a</p> <p>20 comprehensive review of the literature regarding talc</p> <p>21 and its ability to migrate to the ovaries from the</p> <p>22 perineum?</p> <p>23 MS. AHERN: Objection. Form.</p> <p>24 THE WITNESS: No, I disagree. I think I did. In</p> <p>25 fact, I reviewed her studies which she claims supported</p>	<p style="text-align: right;">Page 320</p> <p>1 Would you agree with me that you haven't done</p> <p>2 a comprehensive search of the epidemiologic studies out</p> <p>3 there on talc and ovarian cancer; in fact, you only</p> <p>4 named a few in your reference materials?</p> <p>5 MS. AHERN: Objection. Form.</p> <p>6 THE WITNESS: Well, as I said at the beginning, in</p> <p>7 previous depositions and in the trial, I had reviewed</p> <p>8 many of the epidemiologic studies to, frankly, get up</p> <p>9 to speed on them because I -- up until 2015, I hadn't</p> <p>10 read all those studies, but at that time, I reviewed</p> <p>11 all -- you know, there was many that I thought were</p> <p>12 relevant. So I did review them at that time.</p> <p>13 I didn't review them this time because I felt,</p> <p>14 well, I've done that in the past. And my focus at this</p> <p>15 deposition would be more on ovarian carcinogenesis from</p> <p>16 the standpoint of the gynecologic pathology.</p> <p>17 BY MR. DEARING:</p> <p>18 Q Are you aware that quite a few epidemiology</p> <p>19 study and meta-analyses have actually been published</p> <p>20 since 2015, since you testified?</p> <p>21 A There have been some. And, like, I looked at</p> <p>22 some of these abstracts. Didn't look like it changed</p> <p>23 much.</p> <p>24 Q Well, you haven't looked at the Taher study;</p> <p>25 right?</p>
<p style="text-align: right;">Page 319</p> <p>1 migration, and I added other studies.</p> <p>2 BY MR. DEARING:</p> <p>3 Q With regard to the issue of inflammation, you</p> <p>4 had not seen the Saed study that we started to go over.</p> <p>5 You didn't recite the Ness 1999 study. You just saw</p> <p>6 the Godleski 2019 study for the first time today.</p> <p>7 So there are significant studies that you did</p> <p>8 not consider in forming your opinions today; correct?</p> <p>9 MS. AHERN: Objection. Form.</p> <p>10 THE WITNESS: Well, I can tell you -- and I didn't</p> <p>11 analyze the Saed study because a number of other</p> <p>12 experts looked at it, and I did read their reports</p> <p>13 prior to this deposition and they felt that the studies</p> <p>14 were terrible, basically. And so I didn't find it</p> <p>15 necessary to review it. I found other experts</p> <p>16 reviewing it.</p> <p>17 And right off the bat, he was looking at</p> <p>18 ovarian cancer cells, and that's not what you're</p> <p>19 supposed to be looking at when you're trying to</p> <p>20 establish causation of ovarian cancer. You don't look</p> <p>21 at ovarian cancer; you look at precursor lesions.</p> <p>22 BY MR. DEARING:</p> <p>23 Q Well, you've testified that epidemiology is</p> <p>24 not one of your primary topics that you plan to testify</p> <p>25 about.</p>	<p style="text-align: right;">Page 321</p> <p>1 A Can I see that?</p> <p>2 MS. AHERN: Object to the form.</p> <p>3 (The document referenced below was</p> <p>4 marked Deposition Exhibit 14 for</p> <p>5 identification and is appended hereto.)</p> <p>6 BY MR. DEARING:</p> <p>7 Q So this is the Taher study, and it's not on</p> <p>8 your reference list.</p> <p>9 Have you seen that study before today?</p> <p>10 MS. AHERN: You asked about published studies? Is</p> <p>11 that your question?</p> <p>12 MR. DEARING: Studies.</p> <p>13 MS. AHERN: The question was have there been other</p> <p>14 published studies that you did not review?</p> <p>15 THE WITNESS: I have not seen this study.</p> <p>16 BY MR. DEARING:</p> <p>17 Q Have you reviewed the Health Canada assessment</p> <p>18 that was published on the issue of talc and ovarian</p> <p>19 cancer?</p> <p>20 MS. AHERN: Objection. Form.</p> <p>21 THE WITNESS: The only time I ever was aware of a</p> <p>22 Health Canada study was in reading the deposition of</p> <p>23 Dr. Kane. And she basically said, "Well, the findings</p> <p>24 in the Health Canada study agree with my findings."</p> <p>25 ///</p>

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<p style="text-align: right;">Page 322</p> <p>1 BY MR. DEARING:</p> <p>2 Q You haven't read the Health Canada findings,</p> <p>3 have you?</p> <p>4 A No, I haven't.</p> <p>5 Q With regard to Dr. Saed's 2019 study, are you</p> <p>6 aware that one of the things he looked at and studied</p> <p>7 were fallopian tube cells?</p> <p>8 MS. AHERN: Objection. Form.</p> <p>9 THE WITNESS: I said I didn't read his study.</p> <p>10 BY MR. DEARING:</p> <p>11 Q So, no, you're not aware of the types of cells</p> <p>12 that he studied?</p> <p>13 A No.</p> <p>14 Q I think that's it.</p> <p>15 A Okay. Thank you.</p> <p>16 MS. AHERN: Okay. I have just have a couple -- or</p> <p>17 maybe one or two questions just for clarification.</p> <p>18 THE WITNESS: All right.</p> <p>19 MS. AHERN: Where is my note? Could you do me a</p> <p>20 favor and could you pull up time 15:14:19.</p> <p>21 Hold on a minute. There you go.</p> <p>22</p> <p>23 EXAMINATION</p> <p>24 BY MS. AHERN:</p> <p>25 Q So, Doctor, you were asked repeatedly today</p>	<p style="text-align: right;">Page 324</p> <p>1 A Yes.</p> <p>2 Q The next question you were asked by</p> <p>3 Mr. Dearing is:</p> <p>4 "Are you saying that all of the</p> <p>5 plaintiffs' experts, the 30 or so</p> <p>6 plaintiff experts that you know about,</p> <p>7 are not good scientists."</p> <p>8 And you said, "I didn't say that."</p> <p>9 And then he asked you:</p> <p>10 "Okay. Well, my question is do you</p> <p>11 agree with me that good scientists can</p> <p>12 have differing opinions about cancer</p> <p>13 etiology?"</p> <p>14 You said:</p> <p>15 "It's neither good or bad; I'm</p> <p>16 saying that reasonable people, looking</p> <p>17 at all this data, in my opinion, would</p> <p>18 not disagree that this is -- that talc</p> <p>19 causes ovarian cancer."</p> <p>20 Is that consistent with your opinions on --</p> <p>21 that you've given today on talc and ovarian cancer as</p> <p>22 it's written --</p> <p>23 A That's a little bit of a confusing statement,</p> <p>24 I agree. It's kind of a double negative, "not</p> <p>25 disagree." So my view is -- I'm sorry.</p>
<p style="text-align: right;">Page 323</p> <p>1 about your opinions on ovarian cancer and talc and</p> <p>2 whether or not you thought talc caused ovarian cancer.</p> <p>3 Do you remember throughout the day?</p> <p>4 A Yes.</p> <p>5 Q Okay. There are just a couple of question and</p> <p>6 answers that I want to go over with you, and then I'm</p> <p>7 going to ask you a question. And I think -- because we</p> <p>8 need some clarification on something.</p> <p>9 You were asked the question:</p> <p>10 "Would you agree that good</p> <p>11 scientists can have differing opinions</p> <p>12 about cancer etiology?"</p> <p>13 And you responded:</p> <p>14 "That's a very, very general</p> <p>15 question. But if I frame it with the</p> <p>16 talc litigation, I would venture to say</p> <p>17 that a reasonable scientist viewing --</p> <p>18 viewing all, viewing the totality of</p> <p>19 this data, I don't think anyone would</p> <p>20 agree to say that talc causes ovarian</p> <p>21 cancer."</p> <p>22 Do you see that?</p> <p>23 A Yes.</p> <p>24 Q Is that consistent with your opinions on talc</p> <p>25 and ovarian cancer?</p>	<p style="text-align: right;">Page 325</p> <p>1 Q Sorry. And my next question was, in response</p> <p>2 to that question, what did you intend to say?</p> <p>3 A What I had said earlier. And you can go back</p> <p>4 and cite the same thing again, that looking at the</p> <p>5 totality of evidence and data that's presently</p> <p>6 available, I don't think anyone would agree to say that</p> <p>7 talc causes ovarian cancer.</p> <p>8 MS. AHERN: Okay. That's all the questions I have.</p> <p>9 Thank you.</p> <p>10</p> <p>11 FURTHER EXAMINATION</p> <p>12 BY MR. DEARING:</p> <p>13 Q Doctor, you just testified that you have not</p> <p>14 looked at the totality of all the evidence, that there</p> <p>15 are some studies you have not seen and have not looked</p> <p>16 at.</p> <p>17 So do you agree with me that you have not</p> <p>18 considered the totality of all the evidence?</p> <p>19 A Well, "totality," insofar as what is --</p> <p>20 looking at available, but -- I didn't look at every</p> <p>21 single study, but I think if you put it all into</p> <p>22 perspective, as I mentioned when you asked me that</p> <p>23 earlier, is that you read a number of studies and</p> <p>24 things start to fall in place. And another one study</p> <p>25 isn't going to change it.</p>



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<p style="text-align: right;">Page 326</p> <p>1 MR. DEARING: Okay.</p> <p>2 MR. ZELLERS: Thank you, everyone.</p> <p>3 VIDEO OPERATOR BROWN: The time is now 6:23. This</p> <p>4 concludes the deposition. Going off the record.</p> <p>5 (The deposition proceeding was concluded at 6:23 P.M.)</p> <p>6</p> <p>7 --ooOoo--</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 328</p> <p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition over carefully and</p> <p>4 make any necessary corrections. You should state the</p> <p>5 reason in the appropriate space on the errata sheet for</p> <p>6 any corrections that are made.</p> <p>7 After doing so, please sign the errata sheet</p> <p>8 and date it.</p> <p>9 You are signing same subject to the changes you</p> <p>10 have noted on the errata sheet, which will be attached</p> <p>11 to your deposition.</p> <p>12 It is imperative that you return the</p> <p>13 original errata sheet to the deposing attorney within</p> <p>14 thirty (30) days of receipt of the deposition transcript</p> <p>15 by you. If you fail to do so, the deposition transcript</p> <p>16 may be deemed to be accurate and may be used in court.</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
<p style="text-align: right;">Page 327</p> <p>1</p> <p>2</p> <p>3 CERTIFICATE</p> <p>4 OF</p> <p>5 CERTIFIED SHORTHAND REPORTER</p> <p>6</p> <p>7 The undersigned Certified Shorthand Reporter of</p> <p>8 the State of California does hereby certify:</p> <p>9 That the foregoing proceeding was taken before</p> <p>10 me at the time and place therein set forth, at which</p> <p>11 time the witness was duly sworn by me;</p> <p>12 That the testimony of the witness and all</p> <p>13 objections made at the time of the examination were</p> <p>14 recorded stenographically by me and were thereafter</p> <p>15 transcribed, said transcript being a true and correct</p> <p>16 copy of my shorthand notes thereof;</p> <p>17 That the dismantling of the original transcript</p> <p>18 will void the reporter's certificate.</p> <p>19</p> <p>20 In witness thereof, I have subscribed my name</p> <p>21 this date: _____.</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> <p style="text-align: right;">PAMELA COTTEN, CSR, RDR Certificate No. 4497 Certified Realtime Reporter</p> <p>(The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)</p>	<p style="text-align: right;">Page 329</p> <p>1 -----</p> <p>2 E R R A T A</p> <p>3 -----</p> <p>4 PAGE LINE CHANGE</p> <p>5 _____</p> <p>6 REASON: _____</p> <p>7 _____</p> <p>8 REASON: _____</p> <p>9 _____</p> <p>10 REASON: _____</p> <p>11 _____</p> <p>12 REASON: _____</p> <p>13 _____</p> <p>14 REASON: _____</p> <p>15 _____</p> <p>16 REASON: _____</p> <p>17 _____</p> <p>18 REASON: _____</p> <p>19 _____</p> <p>20 REASON: _____</p> <p>21 _____</p> <p>22 REASON: _____</p> <p>23 _____</p> <p>24 REASON: _____</p> <p>25</p>

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ACKNOWLEDGMENT OF DEPONENT

I, \_\_\_\_\_, do hereby  
certify that I have read the foregoing pages, and that  
the same is a correct transcription of the answers given  
by me to the questions therein propounded, except for  
the corrections or changes in form or substance, if any,  
noted in the attached Errata Sheet.

\_\_\_\_\_  
ROBERT KURMAN, M.D. DATE

Subscribed and sworn to  
before me this

\_\_\_\_\_ day of \_\_\_\_\_, 20\_\_.

My commission expires: \_\_\_\_\_

\_\_\_\_\_  
Notary Public

<b>A</b>				
<b>A.M</b> 1:15 7:2,6	<b>acknowledge</b>	<b>adequately</b>	158:14 170:20	210:2,9,18
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